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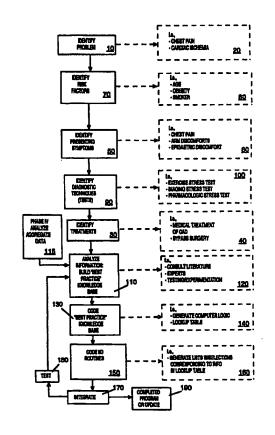
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(54) Title: SYSTEM FOR PROVIDING RECOMMENDATIONS TO PHYSICIANS AND FOR MANAGING HEALTH CARE DATA

#### (57) Abstract

The present invention is directed to a system for supporting the decision making of a physician. Based on input data concerning a patient and a "best practice" knowledge base, the system provides recommendations to the physician, which the physician considers when deciding what action to take. The invention is also directed as helping to ensure that all the relevant data is input and stored in a relational database. The invention includes a method for setting up the "best practice" knowledge base, implementing the knowledge base, and improving the knowledge base using the data stored in the relational database. A specific embodiment directed to diagnosing and treating possible cardiac ischemia is disclosed.



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# SYSTEM FOR PROVIDING RECOMMENDATIONS TO PHYSICIANS AND

# FOR MANAGING HEALTH CARE DATA

5 RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119(e) based on the disclosure of U.S. Provisional Application Serial No. 60/050,978, entitled "SYSTEM FOR PROVIDING RECOMMENDATIONS TO PHYSICIANS AND FOR MANAGING HEALTH CARE DATA," by Kevin J. Graham and John R. Lesser, filed on June 19, 1997.

#### **BACKGROUND OF INVENTION**

The invention is an application of decision support technology to the medical field using computers and relates to the fields of medical diagnosis and treatment, as well as to data processing and recordkeeping. The invention provides decision support to physicians based on data entered from a standard clinical contact such as a physician, nurse, or physician assistant. The invention also generates reports based on a database of diagnostic evaluations performed by physicians and updates the decision support recommendations based on an analysis of the aggregate data.

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## 1. Field of The Invention

It is critical that health care providers correctly diagnose and treat individuals with health problems. Health care providers must provide an accurate diagnosis and complete and appropriate treatment in an economical and efficient manner.

In order to properly diagnose and treat an individual's potential health problem, the individual's past medical history and other information may be needed for evaluation by the health care provider. Thus, the health care provider must maintain detailed records on each individual who presents for diagnosis and/or treatment. An economical system for efficiently managing and utilizing these records is necessary to provide proper service.

It is necessary for health care providers to maintain detailed longitudinal records of patients with chronic diseases. The individual may

need to undergo further testing, treatment and/or monitoring. Many patients need to return for a follow up examination to assess the progression of the medical problem, a prior test, or the results of an earlier treatment. The diagnosis (including testing), treatment, and follow up must be competent and economical.

The invention establishes a system which assists the health care provider in its mission to provide competent and economical service.

# 2. Description of Related Art

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Previously, an individual's diagnosis and treatment were recorded on documents and forms. These forms were filed manually in file folders and stored in a central location at the health care provider's place of business. Additionally, some individuals kept their own copies of their past medical diagnosis and treatment. These manual systems of the prior art are cumbersome and inefficient. It is difficult to locate the appropriate forms, and it is possible for forms to be lost or destroyed.

With the advent of computer technology, many health care providers have attempted to computerize the forms of the prior art. The health care providers who attempted to standardize these forms have met with mixed results. However, the result of this "computerization" has been merely to expensively record standard medical practices by transferring the old paper based system to a computer without attempting to aid physicians in patient diagnosis and treatment selection.

The forms may be difficult to read and may contain incomplete information.

Computerized forms are not a major improvement in the sense that they do not use the capabilities inherent in computer technology. They do not provide an analysis of data and do not synthesize the data to form a recommended course of action to aid in accurate patient diagnosis. Computerized forms do not synthesize data and provide a performance evaluation of a physician or health care facility.

The conventional computerized format shares the shortcomings of historical documents and folders in that the forms may be incomplete and 5

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the coding system employed is based on financial reimbursement and not structured to provide the clinical "best practice."

In the prior art, suspected cardiac chest pain has been diagnosed and treated based on an individual physician's knowledge and ability. An embodiment of the present invention assists a physician to diagnose and treat suspected cardiac chest pain via aggregate knowledge and using the expertise of cardiac specialists.

What is needed is to improve the prior art.

What is needed is a system which aids in the diagnosis and treatment of a patient based on symptoms and signs, not on an already established diagnosis.

What is needed is a system which aids in the diagnosis and treatment of suspected cardiac chest pain.

What is needed is a system for informing a physician that he/she is deviating from a recommended course of treatment, but which allows for deviations in order to potentially identify better approaches in establishing what is the "best practice."

What is needed is a computerized system which identifies and supports proposed courses of treatment to a physician.

What is needed is a computerized health care system, which generates reports and statistical analyses concerning the medical service at a health care institution.

What is needed is a system for ensuring that a physician's diagnosis and treatment plan is fully recorded, in order to help provide feedback to individuals and groups of physicians, and a system designed to change and improve physician practice.

#### **SUMMARY OF INVENTION**

The invention is a system which supports a physician performing a diagnostic evaluation and treatment on a patient. The information concerning this evaluation is stored as part of the patient's medical history in a database. An exemplary embodiment is disclosed which relates to a

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system for aiding in the diagnostic evaluation and treatment of chest pain. This embodiment is directed at diagnosing and treating cardiac ischemia, which is a condition resulting in low blood flow to the heart.

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To assist the physician in the evaluation and treatment of a patient, the present invention provides decision support and presents a reasonable course of action, such as tests to run or treatments to consider based on the patient's symptoms, risk factors, or the results of an earlier test. The physician may choose a recommended or a nonrecommended course of action. In the case where the physician chooses a nonrecommended action, the system will notify the physician that he is deviating from a recommended action. The physician then enters reasons why the recommended action was not followed.

By storing the diagnostic evaluations and treatment decisions (i.e. work-ups) in a database, the system is able to generate reports which are useful for the health care provider. In the chest pain example, the reports include, for example, work-up (i.e. diagnostic evaluation and treatment) reports, pretest assessments, stress tests, angiograms, work-ups per physician, pretest assessments per physician, stress tests per physician, angiograms per physician, facilities, patients, pretest assessment changes, stress test changes and angiogram changes.

The invention of the present system prompts the physician to enter data from menus or lists. The system does not allow the physician to proceed unless a sufficient amount of data is entered. Accordingly, the process of the present invention helps ensure that the evaluation information recorded in the database is complete.

It is an object of the invention to use stored data to assist a physician in diagnosing and treating the patient.

It is an object of the invention to assist a physician in the diagnosis and treatment of a patient based on clinical information entered by the physician.

It is an object of the invention to assist a physician in the diagnosis and treatment of chest pain.

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It is an object of the invention to inform a physician when the physician deviates from a recommended course action, but allow for deviations based on professional judgment to identify better diagnostic and treatment methods.

It is an object of the invention to recommend proposed courses of action to a physician, such as tests to conduct or treatments to follow.

It is an object of the invention to provide a computerized health care system, which generates reports and statistical analyses concerning the medical service at a health care institution or group of health care institutions.

It is an object of the invention to provide an aggregate record of similar diagnoses and treatments to a health care system in order to improve diagnostic and treatment methods.

It is an object of the invention to help ensure that a physician's diagnosis and treatment are fully recorded.

It is an object of the invention to analyze the aggregate data and refine/ change the decision support system based on the outcome of the previously recommended diagnoses and treatments.

# 20 **DESCRIPTION OF THE DRAWINGS**

Figure 1 is a block diagram generally showing "Phase I" and "Phase IV" embodiments of the present invention, including the steps for obtaining information for use in the hardware of Figure 2.

Figure 2 is a diagram showing the hardware components of the present system in the "Phase II" embodiment.

Figure 3A is a block diagram generally showing the routines used in the Phase II system of Figure 2.

Figure 3B is a block diagram generally showing the routines within the Evaluation Routine 600 of Figure 3A.

Figures 4A, 4B, and 4C are exemplary screen displays from the routines shown in Figure 3A.

Figures 5 is a block diagram showing the Symptoms Subroutine of the

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Evaluation Routine shown in Figure 3B.

Figures 6A, 6B, and 6C are exemplary screen displays from the Symptoms Subroutine shown in Figure 5.

Figure 7 is a block diagram showing the Risk Factor Subroutine of the Evaluation Routine shown in Figure 3B.

Figures 8A, 8B are exemplary screen displays from the Risk Factor Subroutine shown in Figure 7.

Figure 9 is a block diagram of the Post Risk Selection Subroutine from the Evaluation Routine shown in Figure 3B.

Figure 10 is a block diagram of the Angiography Subroutine of the Evaluation Routine shown in Figure 3B.

Figures 11A and 11B are exemplary screen displays from the Angiography Subroutine shown in Figure 7.

Figure 12 is a block diagram of the Stress Test Subroutine of the Evaluation Routine shown in Figure 3B.

Figures 13A, 13B, 13C, 13D, 13E, and 13F are exemplary screen displays from the Stress Test Subroutine shown in Figure 12.

Figure 14 is a block diagram of the Post Test Recommendation Subroutine of the Evaluation Routine of Figure 3B.

Figure 15 is a block diagram of the System Installation Software.

Figure 16 is a block diagram of a screen display used to enter a password, for the systems of Figure 15 and Figure 17.

Figure 17 is a block diagram of the Administrative Software used in Phase III of the invention.

25 Figure 18 is an exemplary screen display of the display options step shown in Figure 17.

Figure 19 is an exemplary screen display of the system maintenance option shown in Figure 18.

Figure 20 is an exemplary screen display of the export data option shown in Figure 19.

Figure 21 is an exemplary screen display of the generate reports option shown in Figure 18.

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Figures 22A and 22B are exemplary screen displays (reports) generated in response to the stress test option 903 shown in Figure 21.

Figure 23 is an exemplary screen display (report) generated in response to the workups per physician option 905 shown in Figure 21.

Figure 24 is an exemplary screen display (report) generated in response to the physicians option 907 shown in Figure 21.

Figures 25A and 25B an exemplary screen displays (reports) generated in response to the pretest assessment changes option 909 shown in Figure 21.

Figure 26 is an exemplary screen display generated in response to the statistics option of Figure 18.

Figure 27 is an exemplary screen display of statistical graph generated in response to selection of the workups per physician option of Figure 26.

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#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is a system which enables a physician to follow a guided diagnostic evaluation and treatment recommendation for a patient (a "work-up" or "evaluation"). This "work-up" allows a physician to make a diagnosis and to establish the probability, in a specific embodiment, of whether significant coronary disease is present and to assess its degree of severity. The "work-up" also includes symptoms and signs observed by the physician, the results of tests performed on the patient or conclusions reached by the physician, as well as any unique facts or circumstances specific to the patient. The "work-up" conducted on the patient is stored as part of the patient's medical history in a computer database. The evaluation or "work-up" may also include information related to the treatment (actual and/or recommended), if desired.

The invention involves four "phases" of operation. In the first phase, shown in Figure 1, the information necessary to run the system, the "knowledge base" is obtained. This information is used as the basis for providing recommendations to physicians based on the physician's

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observations, patient information, test results, etc.

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In the second "phase," shown in Figures 2-14, the system is used by physicians in their practice. The physicians utilize the present invention to support their courses of action. The invention provides recommendations/ suggestions to the physicians based on input data. The physicians consider the recommendations using their professional judgment, and decide whether to follow the recommendations. The "work-ups" are stored in a central database and are accessible to all the physicians.

In the third "phase," shown in Figures 2 and 16-27, the system is used by a system administrator to generate reports and statistical graphs based on the stored "work-ups." The system administrator may or may not be the person who installed the system of Phase II, as shown in Figure 15.

In the fourth "phase," shown in Figure 1, the decision report recommendations are periodically refined and updated after a review of the aggregate data and in view of the results of the latest research as determined by an expert review panel.

Thus, the present invention provides a system for recommending courses of action to a physician and compiles the physicians' actions and patient's data in a database. The system also generates reports and statistical analyses based on the data. The system updates recommendations periodically to strive to achieve the "best practice."

#### I. System Phase I: Developing A Knowledge Base and Code.

This invention uses a system/process known as the "best practice," in that the best available clinical information is used. This means that the system has the "best" clinical information available and will provide consistent recommendations based on an action's likelihood of success in a specific patient. The "best practice" uses information that is thought to be the most advanced in the field by the practicing experts in the field. Of course, the system could be set up in an alternative embodiment to recommend the most economical procedures in view of the potential health risks. This alternative is not the preferred embodiment, but may be easily

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implemented by focusing on different criteria in the Phase I process.

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Figure 1 shows Phase I of the invention. In this phase the system obtains the information necessary to form a "knowledge base" of information. The knowledge base is the information which allows a recommendation to be given based on previously known data and, if necessary, various algorithms.

As shown in Figure 1, the first step 10 is to identify the problem. In a preferred embodiment, the problem is chest pain, i.e. cardiac ischemia 20.

The next step is to identify factors which tend to indicate an increased risk 70 of the medical problem, here cardiac ischemia, using the "best practice" process (meaning that the risk factors chosen are the ones which "best" indicate or refute the problem). The factors, known as "risk factors" include old age, obesity, and status as a smoker, among others 80 for cardiac ischemia. The risk factors for chest pain are more fully discussed with reference to Figures 7-9 herein.

Next, the presenting symptoms are identified 50, using the "best practice" system. For the chest pain embodiment, the presenting symptoms include: chest pain, arm discomfort, epigastric discomfort, etc. . . 60. The presenting symptoms are more fully discussed with reference to Figures 5 and 6 herein. The presenting symptoms may either tend to indicate cardiac ischemia or tend to negate it. When a symptom negates the medical problem undergoing evaluation, the symptom is helpful because it indicates that the problem is not present.

The "best practice" process is again used, this time to identify the available diagnostic testing techniques 90 used in the diagnosis of the problem. The results of the diagnostic techniques or tests support or reject the existence of the problem in an individual. The available diagnostic techniques for chest pain include, among others, stress tests. The specific stress tests are exercise stress tests, imaging stress tests, and pharmacologic stress tests 100. These specific tests, and other tests, are described more fully with respect to Figures 10-13 herein.

The next step is to identify existing treatments 30 for the problem.

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Treatments for patients presenting for possible cardiac ischemia are, for example, medical treatment of coronary artery disease (CAD), interventional cardiology procedures, and bypass surgery 40. Treatments, and the other information that is identified in Phase I, are identified from the medical literature, experts in the field, experimentation and validation, or other techniques.

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The information is then analyzed 110 to determine all the possible presenting symptoms, risk factors, and diagnostic techniques, and as a result a "knowledge base" is built. The analysis includes identifying all the information necessary to obtain the symptoms, risk factors, and the information necessary to conduct diagnostic tests, as well as the information obtained from the results of diagnostic tests. The analysis uses the "best practice" technique 120 to determine the "best" techniques for correctly diagnosing the patient. The analysis may also consider other information not falling into the previously described categories, such as patient signs or conditions. As a result, in Phase II the "best" diagnostic techniques and treatments are recommended to the physician.

The "best practice" knowledge base is coded into computer routines 130 and data in the next step. The computer is configured to accept the data needed by the "best practice" analysis and to provide a consequent "best" recommendation. Figures 5-13, Table 1, Table 2, and the Appendix show one example of the "best practice" computer routines 140 for the chest pain embodiment, as determined from the analysis performed by the present inventors.

The data for analysis by the "best practice" routines must be selected or entered by the physician/user. A staff member, such as a physician assistant, or even the patient, may enter/select the data. Therefore, input/output routines must be coded 150 into the "best practice" routines. The input/output (I/O) routines are important because they are designed to elicit all the necessary information from the physician before proceeding to the next request for input or before providing output. The I/O routine may be developed (using known methods) to await the entry of one field of

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information before providing output or before allowing entry of other fields of information. This means that each field of information must be entered. Using this type of I/O system, it is highly likely that the evaluation will contain a complete record of all the pertinent information known to the physician. For example, in Figures 6B and 6C, the "initial clinical impression" selection cannot be made unless (and is preferably not displayed until) suitable "presenting symptoms" are first entered. Likewise, in Figures 8A, 8B, 13C, 13E and 13F it is preferred not to display a recommendation or option (in the last righthand column) until data for each preceding column is present. In an alternative embodiment, each succeeding option for selection or data entry in the I/O system of the present invention would not be displayed until the preceding information was entered or selected.

Preferably the I/O routines are in the form of lists 160 (for example, as shown in Figure 6B). The options in the list are toggled by the physician, preferably by moving a cursor (via mouse or keyboard) over the option and then typing a "select" command, i.e. such as a mouse button. In some cases, more than one option may be selected. For example, Figure 8A shows both the "HTN" and "Diabetes" options selected from the "Risk Factor" list of options.

A "help" box is preferably used with and encoded with the I/O routines of the present invention. When the cursor overlays a possible selection or data entry field the "help" box displays information concerning the selection. For example, in Figure 4A, the cursor is over the "Next Screen" selection. In this case, the "help" box states "Choose this option to go to the next screen." Multiple "help" boxes may be used, one for the screen generally, and one for the selection. An example of multiple "help" boxes is shown in Figure 13D at 163, 165.

A feature improving the usability of the present invention is presenting terms or definitions <u>only</u> at the time they are needed for the particular decision.

The "best practice" routines are integrated 170 with the I/O routines

so that the necessary information is entered/selected when it is needed.

The combination of the coded "best practice" routines and the simple and informative I/O routines results in an easy to use and effective system, which maintains all the critical information available to the physician.

The system uses "evaluation software" 340 to provide recommendations to the physicians, and "administrative software" 330 to maintain the system and generate reports.

Preferably, the system is next tested 180 until it has achieved a high degree of reliability. During testing, the analysis and building of the "knowledge base" 110, the coding of the "best practice" routines 130, the coding of the I/O routines 150, and the integration 170 continues. Preferably a test group of patients is used to help determine patient safety, physician acceptance, and improve the ability of the system to accurately identify disease. A validation study at a hospital may be part of the testing process.

This enables the system to be fine-tuned and peer-reviewed before it is completed 190 and released for general use.

#### II. System Phase II

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Phase II of the system is for the use of physicians, when appropriate, in their daily practice.

#### II.1 Hardware Components.

Figure 2 shows the hardware components of the present system which are generally used in the Phase II embodiment (as well as the testing stage of the Phase I embodiment).

As shown in Figure 2, the system 200 utilizes a computer network 210, including a server 220, with database 230, connected to an administrative computer terminal 240 and a number of local computers 250 (preferably personal computers). The computer network 210 may be connected by a firewall & modem 260 to remote computers 280 using telephone communications and telephone network 270. The remote

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computers may connect by modem 290 to the telephone network 270 or be connected in their own network 300 which is, in turn, connected by modem 290 to the telephone network. Each computer has an input device such as a keyboard 300, a display 312 or monitor, and may have a printer 320, if desired.

The database 230 is preferably a relational database.

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The hardware configuration of this system allows the data from the server 220 to be available to any of the local 250 or remote 280 computers. Each computer 280 is in operative communication with the server and database. The remote computers may be connected via ordinary telephone lines, via the internet, via a dedicated computer network, or via other communications media.

In the simplest embodiment (not shown) the system merely consists of one computer connected to the database. In this system, the computer functions as the administrative unit as well as the input device, and the computer's hard disk drive or floppy disk drive stores the database of information.

The computers 250, 280, except for the administrative unit 240, are each located at the place where the physician performs either a diagnosis or a treatment. The physician uses the input 300 of the computer to provide data concerning the patients and observes recommendations and confirmation of the entered information on the display 310 or printer 320. The computer 250, 280 used by the physician accesses the database to obtain the stored information required for it to function properly.

While each computer 250, 280 could execute software stored at the server, it is desired in the preferred embodiment that each computer 250, 280 is loaded with its own copy of the "evaluation software" 340 of the present invention. The speed of this type of system is improved over the system which executes software stored at the server 220. The administrative computer is loaded with "administrative software" 330 of the present invention. There may be one or several administrative computers 240, each loaded with the administrative software 330 of the present

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invention.

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# II.2. Software Routines- General Overview.

The present invention provides recommended actions to physicians, but is not designed to supercede, question, or substitute for, the physician's professional judgment. The recommendations are to be used by the physician as a decision support tool during the physician's decision process. This may be stated in an introductory screen prior to actually executing any software routines. The introductory screen (not shown) may state, for the chest pain embodiment described herein:

"This physician decision support tool is designed to be an informational guideline solely for use by licensed physicians in aiding their clinical diagnosis of possible ischemic cardiac chest pain. This tool was validated by a prospective study conducted at (hospital name), on (number of) patients from (dates). The information derived from that study and contained herein may not apply in every instance to an individual patient or the symptoms presented by such patient. This tool should therefore not be construed as individualized medical advice and is not intended to be a substitute for the individualized medical advice and advice and clinical judgment of a licensed physician."

The introductory screen (not shown) is preferably displayed prior to running the Phase II routines described herein.

Figure 3A is a block diagram generally showing the operation of the evaluation software 340 of the Phase II embodiment. As shown in Figure 3A, the Select Facility Routine 400 is executed. This routine prompts the physician to enter the facility at which the computer 250, 280 is located. This may be done by either typing the facility name or selecting a facility from the list of facilities which exist in the database 230. An example of a facility is the name of the hospital or clinic. This routine is optional because the facility could be preprogrammed into the physician's computer and would not need to be entered. Also, in the case where there was only one

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facility per database, the facility would not need to be entered. An example of a screen display 405 for the Select Facility Routine is shown in Figure 4A.

After entering the facility, the Select Physician Routine 410 is executed. This routine prompts the physician 420 to enter his/her name into the computer. The physician also indicates 420 whether their status is the primary care physician or a consulting physician. Alternatively, the physician would choose a name from a primary care physician list or consulting physician list, thus, simultaneously entering the status of the physician as well as the physician's name. The physician also enters 420 his/her own personal physician ID code, which is preferably not displayed on the computer screen. The physician is only allowed to proceed if the physician ID code is correct. This is shown at the decision box 440.

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If the "select facility" routine is used, the "select physician" routine only allows the physician to proceed if the physician is authorized at with the previously entered facility. This is shown by the second decision box 440.

In either case, if the physician is denied access a "not authorized" message is displayed 450 and the physician has another opportunity to enter the correct information 420. Additional security features known in the art may be incorporated into the present system but are not specifically discussed herein. An example of one screen display 415 for the Select Physician Routine 410 is shown in Figure 4B.

The next routine is the Patient Identification Routine 460, which requires the entry of a patient's identification number 470, such as the patient's Social Security Number. If the patent's identification number is not stored 480 within the database, the Add Patient Routine 490 prompts the physician to enter the patient's relevant information. This information, for example, is the name of the patient, the patient's gender, the patient's race, and the current date. The patient information is displayed for verification 495 by the physician, as shown for example in the screen display 465 of Figure 4C.

The next routine is the Select Practice Routine 560. This routine

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displays further nonlimiting examples of the practices covered by the present invention, for example: chest pain, congestive heart failure, valvular heart disease, etc. . . . An example of a display screen 505 that includes the Select Practice Routine list 515 is shown in Figure 6A. Because the system of the present invention will be updated periodically to add additional areas of medicine to its coverage, this screen allows the physician to select the area undergoing investigation for the entered patient.

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Medical practitioners will realize that not every conceivable symptom will need to undergo processing via the present invention. As a result, the present inventors have provided an Inclusion Criteria Routine 510. This allows the physician to screen out patients who do not fit within the analysis capabilities of the present invention. The inclusion criteria screen is designed as a "gatekeeper" to help ensure that only the type of patients fitting within the analysis capabilities of the invention are processed by the invention. The Inclusion Criteria Routine 510 is closely tied to the scope of the knowledge base. As the complexity of the present invention increases, the inclusion guidelines become broader.

The inclusion criteria are first displayed 572. The physician selects whether the inclusion criteria are met 574 as applied to the patient. If the inclusion criteria are not met the Phase II embodiment restarts, as shown in Figure 3A. If the inclusion criteria are met, the Phase II embodiment continues.

For the chest pain embodiment of the invention disclosed herein, the inclusion criteria is generally as follows: "possible or probable myocardial ischemia presenting as chest pain, arm, jaw, infrascapular, or epigastric discomfort; if patient has chronic chest pain, symptoms must have worsened since previous evaluation; do not use if the patient exhibits any of the following: shortness of breath as a solitary symptom, myocardial infarction within six weeks, congenital heart disease, significant valvular disease, idiopathic dilated cardiomyopathy, or post-heart transplantation." In these latter cases there is an extremely high probability that the patient is not suffering from cardiac ischemia, thus making use of the present

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invention inappropriate for the specific chest pain embodiment described herein.

After the patient is screened for the appropriate inclusion criteria, the evaluation routine 600 is executed. The evaluation routine 600 allows the physician to select the presenting symptoms and/or risk factors and provides a recommendation for further testing or treatment. All of the information concerning the patient, symptoms, risk factors, diagnosis and/or treatment are stored in an evaluation file (not shown) in the relational database 230.

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The Evaluation Routine 600 is the most complicated routine, and is preferably modular in design so that a separate evaluation routine 600 is used for each practice 515 listed in the Select Practice Routine 560. Alternatively, the Evaluation Routine may be one large routine covering every practice 515 listed in the Select Practice Routine 560. One of ordinary skill will generally realize that modular Evaluation Routines may be conceptually simpler in design, but require more overall code when implemented with the other Evaluation Routines. A single Evaluation Routine will generally require less code because sub-routines may be shared between the practices, but will be conceptually more complicated.

The evaluation is complete after the Evaluation Routine 600 is finished executing. At this point, or if the inclusion criteria are not met, the system returns to either the Select Facility Routine 400, Select Physician Routine 410 or Select Patient Identification Routine 460 so that the system may be used for additional facilities, physicians or patients, as appropriate. Preferably the software returns to the "Select Physician" Routine 410 so that the system is available for the next physician who requires its use.

# II.3. <u>Subroutines for the Evaluation Routine in the Chest Pain</u> Embodiment.

Figures 5-13 depict the Evaluation Routine 600 for the chest pain embodiment. As shown in Figure 3B, the Evaluation Routine contains a number of subroutines. The subroutines, for the chest pain embodiment,

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are: the Presenting Symptoms Subroutine 500 (Figures 5,6), the Risk Factor Subroutine 510 (Figures 7,8), the Post Risk Selection Subroutine 520 (Figure 9), the Stress Test Subroutine (Figures 12, 13), the Post Test Recommendation Subroutine 550 (Figure 14), and the Angiography Subroutine 530 (Figures 10,11). When the Evaluation Routine is exited, the evaluation is saved 531 in the database 230.

### A. Presentation Symptoms Subroutine.

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Figure 5 shows the Presentation Symptoms Subroutine 500. The first step, shown in Figure 5, is to ask the physician whether this is a new evaluation. Figure 6A shows a sample display screen 505 when the Presentation Symptoms Subroutine is entered.

If the evaluation is not a new workup, the physician may select "review previous workup" or "finish existing workup" 517, as shown in Figure 6A. When these options are selected 604, the physician selects a prior workup 606 by date and then whether to go to the beginning or end of the workup 608. At this point, the workup is loaded 610 and processing continues at the desired point. Note that evaluations/workups may be saved and exited and virtually any point in the subroutines.

If this is a new evaluation, the physician is prompted to enter the date 612 and the patient's symptoms 614. Preferably, the computer defaults to the current date stored in the computer. Figure 6B shows typical screen display 525 for a new workup.

The possible symptoms are presented in a list for selection 614 by the physician. The displayed symptoms, in this embodiment, are shown in Figure 6B. They are: "chest pain," "arm discomfort," "neck/jaw discomfort," "epigastric discomfort," "shortness of breath," and "palpitations." The physician selects 614 each of the symptoms applicable to the patient.

As usual, the "help" box is used to display further information about a selection underneath the pointer/cursor, or having to do with the page in general. For example, the "help" box 519 of Figure 6A is the same no matter where the cursor is positioned, and states, for example: "shortness of

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breath and/or palpitations alone do not qualify for this guideline." This informs the physician that insufficient data is available to arrive at an initial clinical impression based on just these two symptoms. If the presenting symptoms are insufficient to provide an initial clinical impression, the physician may select "previous screen" or "save and exit" to restart or end the Evaluation Routine.

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After selecting a symptom, the Presentation Symptoms Subroutine processes the symptom to determine if it is sufficient, along with the previously selected symptoms, to provide an initial clinical impression. The subroutine is preprogrammed with the "best practice" system. In this embodiment, any symptoms, except the "shortness of breath" and "palpitations" (either singly or both) are sufficient to provide an initial clinical impression. Thus, if any symptoms are present other than shortness of breath or palpitations 616, the Presenting Symptoms Subroutine proceeds to the selection of an initial clinical impression.

When sufficient presenting symptoms are entered, the "initial clinical impression" options are displayed 618. The physician, using his/her own judgment, selects an initial clinical impression, in this case "definite cardiac ischemia," "probable or possible cardiac ischemia" or "discomfort/pain not from cardiac ischemia," as shown in Figure 6B.

If the initial clinical impression is that "discomfort/pain not from cardiac ischemia" 620, then the evaluation is complete because the physician has decided that the symptoms indicate that cardiac ischemia is definitely not a possibility. At this point the physician is prompted to enter notes 622, if desired. A sample screen 527 where this has occurred is shown in Figure 6C. The Presentation Symptoms Subroutine 500 generates a short report 624 to state the information entered and the conclusion, and saves the evaluation. The report may be printed, at the physician's discretion 626. The Evaluation Routine 600 is then complete.

If the physician's initial clinical impression is "definite cardiac ischemia," or "probable or possible cardiac ischemia" the evaluation routine progresses to the risk factor analysis. The Risk Factor Subroutine is used

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to perform the risk factor analysis.

#### B. Risk Factor Subroutine.

The Risk Factor Subroutine 510, shown in Figure 7, is used to analyze risk factors which may help in the diagnosis of the chest pain. Two sample Risk Factor Subroutine screen displays 535, 537 are shown in Figures 8A and 8B.

First, the physician selects risk factors 630 associated with ischemia. As shown in Figures 8A and 8B, the factors indicating a risk of cardiac ischemia are: age (i.e. male over 55, female over 60), HTN or hypertension (i.e. blood pressure greater than 140/90 or treated for HTN), smoker (i.e. current or quit within last two years), family Hx or history (i.e. first degree relative with known CAD less than 60 years old), obesity (i.e. greater than 30% over ideal body weight), diabetes (i.e. fasting blood sugar greater than 140 mg/dl or treated for diabetes), dyslipidemia (i.e. total cholesterol greater than 240 or LDL (low density lipoprotein) cholesterol over 130 or HDL (high density lipoprotein) cholesterol under 35 in males/45 in females or triglycerides over 240 or treated for dislipidemia), known CAD (previously diagnosed by objective criteria for significant CAD).

When the cursor overlays a risk factor, the "help" box preferably displays information concerning the risk factor. Information is only presented when it would be of help to the user. For example, when the cursor overlays HTN, the "help" box states "blood pressure greater than 140/90 or treated for HTN."

The computer processes the risk factors to determine the "pretest risk for CAD." In the preferred "best practice" embodiment, three or more risk factors (or "known CAD") 632 result in a high pretest risk 634, two risk factors 636 result in an intermediate pretest risk 638, and zero to one risk factor results in a low pretest risk 640.

The pretest risk is then displayed for reference by the physician, and is used by the processing step in formulating a recommendation.

The physician also selects the anginal type 644. As shown in Figure

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8A, the possible types include "typical," "typical/atypical," "atypical." The "help" box may display further information when the cursor overlays the anginal type possibilities. For example when the cursor overlays "typical" the help box displays "Symptoms definitely characteristic of myocardial ischemia, reproducibly precipitated by increased cardiac workload (usually exercise) and relieved promptly with rest or NTG (nitroglycerin). An anginal equivalent in the appropriate setting is also considered typical angina. Shortness of breath alone is not considered an anginal equivalent."

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For "typical/atypical" anginal type the "help" box may state: "Symptoms with characteristics of typical (exertional) and atypical components. Shortness of breath alone is not considered an anginal equivalent."

For the "atypical" anginal type the "help" box may state "Symptoms are possibly due to myocardial ischemia, but have one or more features atypical for angina. Shortness of breath alone is not considered an anginal equivalent."

After entering the anginal type, the physician enters the Canadian Anginal Classification ("C.A.C.") 646, from the list of classifications. The C.A.C. types, which may be described in the "help" box, are listed on the screen when the cursor is over the selection. The type I help box states that this classification applies if ordinary physical activity, such as walking and climbing stairs, does not cause angina; angina present with strenuous or rapid or prolonged exertion at work or recreation.

The "help" box 533 of Figure 8A is shown displaying the further information for C.A.C. type II: Slight limitation of ordinary activity; walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress, or only during the few hours after awakening; walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions. The type III "help" display would relate to a marked limitation or ordinary physical activity; walking one to two blocks on the level and climbing more than one flight in normal conditions. The type IV

classification is broken into two subclassifications, stable and unstable. For the type IV (stabilized), the "help" display would relate to an inability to carry on any physical activity without discomfort; discomfort may be present at rest; rest discomfort has not recurred in 48 hours; no previous or current objective evidence of ischemia at rest (ST depression  $\geq 1$  mm, 80 msec after the J point on EKG. The "help" for the type IV (unstable) classification would state: inability to carry on physical activity without discomfort; discomfort may be present at rest; rest discomfort has occurred within last 48 hours, and/or EKG shows objective evidence of ischemia at rest (ST depression  $\geq 1$  mm, 80 msec after the J point on EKG); type V (atypical chest discomfort (or anginal equivalent) NOT associated with increased cardiac workload (usually exercise), an NOT promptly relieved with rest and/or nitroglycerin).

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The Risk Factor Subroutine processes the information 648 previously entered or already determined from the inputs, namely the pretest risk of CAD (either high, intermediate, or low), the anginal type (either typical, typical/atypical, or atypical), and the C.A.C. (either I, II, III, IV (stabilized), IV (unstable), or V.

The processing of this information 648, in the preferred embodiment, uses a lookup table preset with each of the possible entered conditions. The lookup table is also preset with recommendations. The recommendations correspond to the "best practice" previously discussed, meaning that they are preferred clinical recommendations, as understood by most advanced thinking in the field.

The lookup table used in the processing of risk factors is as follows (note that multiple recommendations may be made and display notes may be shown on the screen):

Table 1: Risk Factor Lookup Table.

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	PROBABILITY	ANGINAL TYPE	C.A.C.	RECOMMENDATION(S)
5	Low Typical		1	Non-Invasive Testing
	Low	Typical	2	Non-Invasive Testing
	Low	Typical	3	Non-Invasive Testing
	Low	Typical	4-S (stabilized)	Non-Invasive
	Low	Typical	4-U (unstable)	NonInvasive/ Angiography Display Note: use of non- invasive testing assumes adequate symptom stability
10	Low	Typical/Atypical	1	Non-Invasive Testing
	Low	Typical/Atypical	2	Non-Invasive Testing
	Low	Typical/Atypical	3	Non-Invasive Testing
	Low	Typical/Atypical	4-S	Non-Invasive
	Low	Typical/Atypical	4-U	Non-Invasive/ Anglography Display Note: use of non- invasive testing assumes adequate symptom stability
15	Low	Atypical	1	No Further Diagnostics/ Non-Invasive Testing
	Low	Atypical	2	No Further Diagnostics/ Non-Invasive Testing
	Low	Atypical	3	No Further Diagnostics/ Non-Invasive Testing
	Low	Atypical	5	No Further Testing/ Non- Invasive Testing
	Intermediate	Typical	1	Non-Invasive Testing
20	Intermediate	Typical	2	Non-Invasive Testing
	Intermediate	Typical	3	Non-Invasive Testing
	Intermediate	Typical	4-S	Non-Invasive/ Angiography Display Note: use of non- invasive testing assumes adequate symptom stability
	Intermediate	Typical	<b>4-</b> U	Angiography
	Intermediate	Typical/Atypical	1	Non-Invasive Testing□
25	Intermediate	Typical/Atypical	2	Non-Invasive Testing

	Intermediate	Typical/Atypical	3	Non-Invasive Testing
	Intermediate	Typical/Atypical	4-S	Non-Invasive
	Intermediate	Typical/Atypical	4-U	Non-Invasive/ Angiography Display Note: use of non- invasive testing assumes adequate symptom stability
	Intermediate	Atypical	1	No Further Diagnostics/ Non-Invasive Testing
5	Intermediate	Atypical	2	No Further Diagnostics/ Non-Invasive Testing
	Intermediate	Atypical	3	No Further Diagnostics/ Non-Invasive Testing
	Intermediate	Atypical	5	No Further Testing/ Non- Invasive
	High	Typical	1	Non-Invasive Testing
	High	Typical	2	Non-Invasive Testing
10	High	Typical	3	Non-Invasive Testing
	High	Typical	<b>4-</b> S	Angiography
	High	Typical	4-U	Anglography
	High	Atypical	1	Non-Invasive Testing
	High	Atypical	2	Non-Invasive Testing
15	High	Atypical	3	Non-Invasive Testing
-	High	Atypical	5	Non-Invasive Testing
	High	Typical/Atypical	1	Non-Invasive Testing
	High	Typical/Atypical	2	Non-Invasive Testing
	High	Typical/Atypical	3	Non-Invasive Testing
20	High	Typical/Atypical	<b>4</b> -S	Non-Invasive/ Angiography Display Note: invasive testing preferred as a first step; non-invasive testing acceptable if symptom stability allows.
	High	Typical/Atypical	4-U	Angiography

The "recommendation" from the lookup table corresponding to the entered information is displayed 650, and highlighted in the list of options. For

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example, Figure 8A shows that the recommendation is "non-invasive testing", and this option is highlighted in the list of options.

In the chest pain embodiment, the recommendation options (shown in Figures 8A and 8B) are testing options, including: (a) no further diagnostics, (b) non-invasive testing, (c) angiography. The recommendation may also be a treatment or combination of two or more of these options, as indicated in the lookup table.

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The recommended post risk options, in this case testing options, are displayed on the computer screen for selection by the physician 650, with the recommendation shown at the top and the recommended options highlighted in a specific color, preferably green. The physician may select 652 any of the possible post risk options, including options which are not recommended.

If the selected post risk option is not a recommended option 654, the physician is prompted to enter reasons for deviating from the recommended treatment 656. A screen display 539 showing this "guideline deviation" is depicted in Figure 8B. The reasons for deviation, as shown in Figure 8B, could be: (a) professional judgment, (b) referral physician's preference, (c) public safety, (d) patient request, or (e) other. Thus, the physician is prompted to carefully consider a situation when he is deviating from a recommended course of treatment.

After entering an option, the Post Risk Selection Subroutine 520 is executed.

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#### C. Post Risk Selection Subroutine.

The Post Risk Selection Subroutine 520, shown in Figure 9, processes the selected post-risk option.

If the selected option is "no further diagnostics" 660, the Post Risk Selection Subroutine allows the physician to enter comments 662, and then ends the Evaluation Routine, saving the evaluation/workup. The physician has decided to forgo further testing.

If the selected option is not "angiography" 664, then it is "non-invasive testing." In this case the Post Risk Selection Routine 520 branches to the Stress Test Subroutine 540. The Stress Test Subroutine 540 is described below with reference to Figures 12 and 13.

If the selected option is "angiography," the Post Risk Selection Subroutine 520 branches to the Angiography Subroutine 530.

#### D. Angiography Subroutine

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The Angiography Subroutine 530, shown in Figure 10, first asks the physician whether the angiography has been completed 670. If the angiography has not been completed, the physician is asked whether an angiography is pending 672. If an angiography is not pending, then the patient must have declined an angiography and the physician is prompted to enter reasons why the patient has declined angiography 674.

If the angiography is pending, the physician is asked whether the angiography has been scheduled 676. If the angiography has not been scheduled, the Evaluation Routine is ended and the evaluation saved. The

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physician will reload the evaluation after the angiography has been scheduled.

If the angiography is pending and scheduled, the physician is asked to enter the date the angiography will occur 678. The Evaluation Routine is then ended and the evaluation saved. The physician will reload the evaluation after the angiography has been completed.

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If the angiography has been completed, then the display 545 shown in Figure 11A is generated. The physician is prompted to enter the date of the angiography 680. The physician then is prompted to select a visual assessment of stenosis, and the general results of the angiography 682. Specifically, the physician may select one or more of the following stenosis options (with information about the stenosis option displayed in the "help" box): (a) left main 50% or greater stenosis (visually assessed diameter stenosis in left main coronary artery of 50% or greater); (b) Other Coronary Arteries- 70% or greater stenosis (severest visually assessed diameter stenosis is 70% or greater in at least one major coronary vessel or first order branch); (c) Other Coronary Arteries- 50-69% stenosis (severest visually assessed diameter stenosis is 50-69% in at least one major coronary vessel or first order branch); (d) Other Coronary Arteries- less than 50% stenosis (severest visually assessed diameter stenosis is less than 50% in at least one major coronary vessel or first order branch).

After selecting the appropriate stenosis options, the physician is prompted to compare the stenosis to any previously observed stenosis (682), as shown in Figure 11A. The options for selection (with "help" text) include:

"new or progressed" (stenosis is new or has progressed in severity since previous coronary angiogram), "previously noted" (the stenosis was noted on a previous angiogram and has not changed significantly), and "no previous angiography" (no prior angiography for comparison).

The Angiography Subroutine next asks the physician for the physician's initial recommendation following angiography 684, as shown in Figure 11B. A list of options 547 is presented for selection, including: "no treatment of coronary artery disease (CAD)," "medical Treatment of CAD," "interventional cardiology procedure," and "coronary artery bypass surgery (CABG)".

After selecting an initial recommendation following angiography 684, the physician enters any notes or data specific to the patient 686, 544. The evaluation is then complete. The Angiography Subroutine and Evaluation Routines end, and the workup is saved.

The Angiography Subroutine 530 may be programmed to recommend an initial recommendation following angiography, in the same manner (lookup table) as previously provided for. However, the embodiment shown herein allows the physician to use his/her judgment in selecting the initial recommendation following angiography.

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#### E. Stress Test Subroutine.

Referring back to the Risk Factor Subroutine 510 (Figures 7, 8A, 8B), and the Post Risk Selection Subroutine 520 (Figure 9) one option following the pretest risk is "non-invasive testing" (Figures 9, 8A, 8B) If this option

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is selected, the Stress Test Subroutine 540 is executed.

### E1: Selecting A Stress Test.

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The Stress Test Subroutine 540 prompts the physician to select from a list of tests 555 which could be performed, shown, for example in Figures 13A and 13B. In the chest pain embodiment, these tests are stress tests. In the present embodiment shown in Figures 13A and 13B, the physician may select from: an imaging stress test, a pharmacologic stress test, or an exercise stress test. The "help" box 557 may provide selection criteria concerning the selection of a stress test, when the cursor overlies the stress test selection. Alternatively, each listed stress test may have an adjacent "help" box to provide selection criteria about the test.

The information criteria for the exercise stress test may be as follows:

(1) preferred stress test for most patients, (2) patient must be able to exercise adequately, (a) double product > 20,000 needed for test, (b) B-blockade may limit heart rate response and decrease sensitivity, (3) EKG (ST segments) must be interpretable at rest, (a) no LBBB, pre-excitation, (b) no resting ST segment abnormalities (examples: digoxin ST changes, left ventricular hypertrophy (LVH) ST segment changes, Ischemic ST depression).

The information criteria for the imaging stress test may be as follows:

(1) most useful for patients with (a) intermediate pre-test probability of CAD,

(b) previous indeterminate stress test with double product > 20,000, (c)

uninterpretable resting EKG (LBBB, pre-excitation, resting ST segment

abnormalities), (2) imaging increases sensitivity and specificity, (3) patient

must be able to exercise adequately, (a) double product > 20,000 needed for diagnostic tests, (b), B-blockade may limit heart rate response and decrease sensitivity, (4) may be useful in patients with known significant CAD to localize ischematic bed.

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The information criteria for the pharmacologic stress test may be as follows: (1) most useful for patients who cannot exercise adequately, (a) severe peripheral vascular disease, (b) other physical limitations, (examples: musculo-skeletal, neurologic disease, general debility), (2) test of choice with previous indeterminate stress test as a result of double product < 20,000, (3) helpful in patients with documented chronotropic incompetence leading to inadequate double product, (a) fixed rate heart pacing, (b) severe B-blockade.

The Stress Test Routine 540 prompts the physician to enter a stress test type 701 (either exercise, imaging, pharmacological, or other). The Stress Test Routine 540 tests to see whether the exercise stress test was selected 700. If the exercise stress test was not selected, the routine checks to see whether the imaging stress test was selected 702. If the imaging stress test was selected, then the physician is prompted to select imaging stress test indications 704, as shown in Figure 13A.

The imaging stress test indications 561, shown in Figure 13A, are presented in a list and the "help" box may display information concerning each test indication when overlaid by the cursor. The imaging stress test indications are (with Help screen information): (a) left bundle branch block (left bundle branch block is present on resting EKG); (b) baseline ST

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segments abnormality (baseline EKG shows ST segment abnormalities that will make definitive ST interpretation with stress nondiagnostic (baseline LVH with repolarization changes); (c) known CAD-localization of ischemic bed (patient has known CAD; localization os ischemic bed desirable for prognosis and/or treatment); (d) on medication known to cause ST segment changes (on medication that is known to cause "false positive" ST segment changes (digitalis)); (e) previously indeterminent stress test (results of previous stress testing inconclusive for diagnosis and/or prognosis of CAD); (f) female under 55 years old (risk group where regular exercise stress testing is thought to have a poorer predictive value because of lower incidents of CAD in this population); (g) other (includes physician discretion).

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The imaging stress test indications are saved in the database 230.

Referring to Figures 12 and 13B, if the exercise stress test has not been selected and the imaging stress test has not been selected, then the pharmacologic stress test has been selected 706. In this case, the physician is prompted to select from the pharmacologic stress test indications 707, as shown on screen 563 in Figure 13B.

The pharmacologic indications 707 shown in Figure 13B (along with the "help" box text) are: (a) inability to exercise due to PVD or peripheral vascular disease (inability to exercise due to symptomatic peripheral vascular disease); (b) inability to exercise other (inability to exercise due to causes other than peripheral vascular disease); (c) previous indeterminate stress test (previous stress test has been indeterminent for diagnosis and/or

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prognosis of CAD); (d) chronotropic incompetence (documented chronotropic incompetence (fixed rate pacing, severe B-blockade)); (e) other ("other" indications for pharmacologic stress testing including "physician discretion"; please enter indication).

The selected stress test indications are saved to the database 230 working file.

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Referring back to Figure 12, if the exercise stress test has been selected, then no indications (in this embodiment) need be entered.

# E2. Selecting Imaging and Pharmacologic Stress Test Types.

With reference again to Figure 12, if the exercise stress test has been selected 700, then the physician is prompted to enter the exercise stress test data 708, as shown on screen 565 in Figure 13C, without first selecting an exercise stress test type (in this embodiment). If the imaging stress test has been selected 702 (Figure 13A), and the imaging stress test indications selected 704 (Figure 13A), then the imaging stress test type must be selected, as shown in Figure 13D, and the imaging data entered 712, as shown in Figure 13E. If the pharmacologic stress test has been selected (Figure 13B) and the pharmacologic stress test indications selected 707 (Figure 13B), then the pharmacologic stress test type 714 must be selected (not shown) and the pharmacologic data entered 716, as shown in Figure 13F. The screen display for entering the pharmacologic stress test type 714 (not shown) would be similar to the screen 567 of Figure 13D (imaging stress test type).

First, with respect to the imaging stress test types shown in on the screen 567 of Figure 13D, the possible types of stress test may be exercise echo, exercise thallium, exercise cardiolite, or "other".

As shown in Figure 13D, the "help" box 165 for the exercise echo imaging stress test may state: (1) most useful for patients with no wall motion abnormality or previous infarction; (2) patient must be able to exercise adequately; (3) must be able to obtain diagnostic echo images; (4) produces resting echo image as secondary benefits.

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The exercise thallium imaging stress test help box may state: (1) most useful for patients with wall motion abnormality or previous infarction; (2) patient must be able to exercise adequately; (3) imaging quality good in almost all patients; (4) delayed valium imaging (24 hours with reinjection), may be helpful to check for viable myocardium in patients with resting perfusion defects.

The help box for the exercise cardiolite imaging stress test may state:
(1) most useful for patients with wall motion abnormality or previous infarction; (2) patient must be able to exercise adequately; (3) imaging quality good in almost all patients.

If desired, the help boxes could also indicate the relative expense of the different tests. For example, the bottom of the exercise echo help box could state "less expensive than exercise nuclear imaging," as shown in Figure 13D. The help box for the exercise thallium test could state at the bottom "more expensive than exercise echo by 2% - 3%." The exercise cardiolite test help box could state at the bottom "more expensive than

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exercise echo by 2 - 3 times." This would enable the physicians to take into account the relative costs of the tests for their patients.

With respect to selecting the pharmacologic stress test type (Figure 12), numerous types may be provided for, including dobutamine echo, adenosine cardiolite, adenosine thallium, dipyridamole thallium, and dipyridamole cardiolite (note that PERSANTINE is the trade name for dipyridamole).

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For the dobutamine echo pharmacologic stress test, the "help" box may state: (1) most useful for patients with normal ventricles or with wall motion abnormality and/or previous infarctions (provides data on possible mycocardial viability); (2) must be able to obtain adequate echo images; (3) may aggravate tachyarrhythmias (atrial fib, v. tach); (4) better test than adenosine/dipyridamole for patients with bronchospastic disease).

For the adenosine cardiolite, adenosine thallium, dipyridamole thallium, or dipyridamole cardiolite pharmacologic stress tests, the "help" box may state: (1) most useful for patients with resting LBBB or potential stress induced tachyarrythmias; (2) useful in patients with normal ventricles, wall motion abnormalities, and/or previous infarctions; (3) imaging quality good in almost all patients; (4) cardiac medications (B-blockade, etc.) and large patient size do not limit its usefulness; (5) may aggravate bronchospasm.

Other types of stress tests can be added to the system, including cardiopulmonary, nuclear, exercise MUGA, etc...., although these are not included in the present embodiment.

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Referring back to Figure 12, after the imaging/pharmacologic stress test types are selected 710, 714, the test data for the pertinent stress test is entered 12, 716.

### 5 E3: Entering the Stress Test Data.

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Again, with reference to Figure 12, if the exercise stress test is selected by the physician, the physician is prompted to enter the exercise test data 708, as shown in Figure 13C. This data includes the testing protocol (Bruce, modified Bruce, Naughton, Balke, other). The double product (heart rate times systolic blood pressure at maximum exercise), exercise time (minutes, seconds), and date performed are also entered.

Next, the physician checks whether any negative/positive subjective results and negative/positive/ indeterminate objective results (by EKG) were observed. The "help" box may display information concerning the subjective and objective results.

For a negative subjective result, the help box may state: "no symptoms compatible with myocardial ischemia, (angina or anginal equivalent); shortness of breath alone is not considered anginal equivalent."

For a positive subjective result, the help box may state: "symptoms compatible with myocardial ischemia (angina or anginal equivalent); shortness of breath alone is not considered anginal equivalent."

For a negative objective result (by EKG), the help box may state: "less than 1 mm ST segment depression 80 msec after the 'J' point in exercise or recovery."

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For a positive objective result (by EKG), the help box may state: "greater than or equal to 1 mm ST segment depression 80 msec after the 'J' point in exercise or recovery."

For an "indeterminate" objective result (by EKG), the help box may state: "ST segments cannot be interpreted with reasonable certainty secondary to baseline ST changes, artifact, medications or physiologic cause ST segment changes, LBBB, pre-excitation, etc..."

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Additionally, a "high risk positive" objective result (by EKG) may be provided as a selection. For this result, the help box may state: "(1) exertional or transient ST segment elevation not subtending a 'Q' wave with symptoms at any level of exercise; (2) exertional or transient ST segment depression > 2 mm 80 msec after the 'J' point at any level of exertion with symptoms of ischemia."

Further, another option in an "other" category, relating to "exertional hypotension" may be provided. The help box for this result may indicate that the result should be selected if "greater than 10 mm Hg drop in blood pressure during exercise."

Referring back to Figure 12, if the physician had selected an imaging stress test 702, he would have already selected the imaging stress test indications 704 and the imaging stress test type 710, as shown in Figures 13A and 13D, respectively.

The physician is then prompted to enter the test data 712, as shown on the screen 569 of Figure 13E. The test data is identical to the data entered in the exercise stress test described previously and shown in Figure

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13C. However, the imaging stress test, shown in Figure 13E, has an additional field specific to the type of imaging test. This field is the "objective special results" field, which lists "negative," "positive," and "intermediate" as required selections for the imaging stress test type selected.

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For a stress echo test, the field relates to "objective results by echo." In this case "negative" may be explained by the "help" box to refer to "no wall motion abnormality consistent with reversible ischemia in exercise or recovery." The "positive" objective result would be caused by "wall motion abnormality consistent with ischemia during exercise," as explained by the "help" box. The "indeterminate" selection corresponds to "assessment of wall motion abnormalities cannot be made with reasonable certainty." Additionally, other options may be added to the "objective results by echo" screen, including a "high risk positive" selection which relates to "large amount of ischemic myocardium with exercise (multiple wall motion abnormalities), left ventricular (LV) dilation with exercise, decreased or unchanged LV ejection fraction with exercise, ischemic area remote from fixed defect."

Similar "help" text is provided for the other types of imaging stress tests provided for by the present invention.

Referring back to Figure 12, if the physician had selected a pharmacologic stress test 706, he would have already selected the pharmacologic stress test indications 707 (not shown) and the pharmacologic stress test type 714 (Figure 13B).

The physician is then prompted to enter the pharmacologic test data 716, as shown in Figures 12, using a display similar to the screen 571 of Figure 13F. The pharmacologic data is identical to the imaging stress test data, previously discussed (Figure 13E) with the following exceptions.

The protocol, double product, and exercise time (as well as the other/ "exertional hypotension") fields are not used for any of the pharmacologic tests. In the case of a dobutamine echo pharmacologic stress test, a "maximum heart rate" field and "maximum dobutamine dose (µg/Kg/Min)" field are added (not shown).

As with the imaging stress test data, the pharmacological stress test data contains an "objective special result" field. This field provides a "negative," "positive," and "indeterminate" selection based on the type of pharmacological stress test.

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The "help" field provides information concerning which special result should be selected. For the dobutamine echo test, "negative" should be selected if the result is "no wall motion abnormality consistent with reversible ischemia during stress." The "positive" selection should occur when "wall motion abnormality consistent with ischemia during stress." The "indeterminate" selection is proper when "assessment of wall motion abnormalities cannot be made with reasonable certainty." Additionally, a "high risk positive" selection may be provided for situations where "large amount of ischemic myocardium identified with stress (multiple wall motion abnormalities), LV dilation with stress, decreased or unchanged LV ejection fraction with stress, and/or ischemic area remote from fixed defect."

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For the adenosine thallium and adenosine cardiolite pharmacological stress tests, "negative" should be selected when "no area of reversible ischemia identified with stress." The "positive" objective result by adenosine thallium or adenosine cardiolite should be selected when "area of reversible ischemia identified with stress." The "indeterminate" selection corresponds to "assessment of perfusion defects cannot be made with reasonable certainty". Additionally, a "high risk positive" selection may be provided for cases where "large amount of ischemic myocardium identified with stress or multiple defects, LV dilation with stress, ischemic area remote from fixed defect, and/or lung uptake (thallium)."

Similar "help" box messages apply for the PERSANTINE cardiolite and PERSANTINE thallium tests, as well as other tests which may be added to the present invention.

After the exercise, imaging, or pharmacologic test data is entered 708, 712, 716, the data is ready for processing.

### E4: Processing the Stress Test Data.

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Referring back to Figures 12 and 13C, in the case of the exercise stress test data being entered, the data is processed 718 for post test risk 720. The preferred embodiment uses a lookup table containing all the permutations of information which are possible in response to the selections and ranges input by the physician. The exercise stress test lookup table (for the Balke testing protocol) is disclosed at pages 2-4 of the Appendix attached hereto. The lookup table for the other testing protocols (Bruce,

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modified Bruce, or Naughton) may be identical to the Balke lookup table, since each results in the "double product" information. The result of the analysis from the lookup table is a post-test risk of either "low," "intermediate," "high," or "indeterminate." The post-test risk is used to obtain a post-test recommendation, using logic chart of Table 2.

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Note that it is unnecessary to include the "high risk positive" option in the lookup table of the Appendix (pages 2-4) because whenever this option is selected, the post-test risk is always set to "high". This is also true with the "exertional hypotension" option. Whenever this option is selected, the post-test risk is always set to "high".

Referring back to Figures 12 and 13E, the imaging stress test analyzes the imaging stress test data 722, 724 in the same way as that previously described for the exercise stress test. The image stress test data is processed by using a lookup table containing the possible permutations of the data which it was possible to enter. The lookup table for the imaging stress test (Bruce testing protocol) is shown at pages 5-34 of the attached appendix. The lookup table for the other testing protocols (Balke, modified Bruce, or Naughton) may be identical to the Bruce lookup table, since each results in the "double product" information. The result of the analysis from the lookup table is a post-test risk 774 of either "low," "intermediate," "high," or "indeterminate." These results are converted into a recommendation via the logic of Table 2.

Note that it is unnecessary to include either the other field/
"exertional hypotension" or the objective special result/ "high risk positive"

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fields in the lookup table. Whenever either of these fields are selected, the "high" post-test risk result occurs.

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Referring back to Figures 12 and 13F, in the case where the pharmacologic stress test data is entered 716, it is processed 726 in a similar manner as that of the exercise and imaging stress tests. The pharmacologic stress test data is processed by using a lookup table containing the possible permutations of the data which it was possible to enter. The lookup table for the pharmacologic stress test (adenosine cardiolite. adenosine thallium, dobutamine echo, dipyridamole (PERSANTINE) cardiolite, dipyridamole (PERSANTINE) thallium) is shown at pages 35-41 of the attached Appendix. The result of the analysis from the lookup table is a post-test risk 728 of either "low," "intermediate," "high," or "indeterminate." The post-test risk is used with the logic of Table 2 to provide a recommended action.

Note that it is not necessary to include the "high risk positive" (special objective result) selection in the lookup table because if this field is selected the result of post-testing will always be a "high" risk.

As previously stated, the processing routines always provide a posttest risk of either "low," "intermediate," "high," or "indeterminate." The posttest risk is then displayed on the computer screen, as shown in Figures 13C, 13E, and 13F.

A post-test recommendation routine 730 then uses its own lookup table to provide a post-test recommendation. The post-test recommendations are selected from one or more post-test options, and may

be a combination of: "no further testing or ischemia treatment," medical treatment of ischemia," "medical treatment and non-invasive retesting," "imaging or pharmacologic stress testing," and "angiography."

The lookup table (with "help" text) is as follows:

## Table 2: Post-Test Risk Recommendations Based on Post-Test Risk

	,	
POST-TEST RISK		RECOMMENDATION(S) & "Help" text
Low	1.	No further testing or ischemia treatment
		(Help text: Patient is either believed to have ischemic coronary artery disease or be adequately treated on current regimen.)
	2.	Medical treatment of ischemia
		(Help text: Patient is believed to have CAD and medical regimen will be intensified.)
Intermediate	1.	Medical treatment and non-invasive retesting
		(Help text: Patient is believed to have CAD, will be given medical treatment and then non-invasive re-tested to determine adequacy of treatment.)
	2.	Angiography
		(Help text: Recommended to define coronary artery anatomy for diagnosis and prognosis.)
High	1.	Angiography
		(Help text: Recommended to define coronary artery anatomy for diagnosis and prognosis.)
Indeterminate	1.	Imaging or Pharmacologic stress testing.
		(Help text: Imaging or pharmacologic stress testing recommended to increase sensitivity/specificity of previous testing for diagnosis and prognosis.)

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The post-test options are displayed 732, with the recommended option displayed at the top and highlighted in the list, as shown in Figures 13C, 13E, and 13F. The "help" box may provide more information, as indicated in the table, on the option on which the cursor is present.

The physician selects a post-test option 732 and, if a non-recommended option 734, enters reasons 736 why the option was selected (in a similar manner to that shown in Figure 8B). As stated previously, the reasons include: "professional judgment," "referral physician preference," "public safety," "patient preference," and "other".

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### F. Post Test Recommendation Subroutine.

After the selection has been entered (Figure 12), the Post Test Recommendation Subroutine 550, shown in Figure 14, is executed.

If the selection was "angiography" 740, the Angiography Routine 530, previously discussed with reference to Figure 10, is executed.

If either "no further testing or ischemia treatment" or the "medical treatment of ischemia" options are selected 742, the workup is completed. The physician enters any relevant comments 746 and the Evaluation Routine ends and saves the workup.

If none of these options were selected, then the "medical treatment and non-invasive retesting" or the "imaging or pharmacologic stress testing" options must have been selected. In this case, the Stress Test Subroutine 540, previously discussed with reference to Figure 12, is executed a second time. This enables the physician to select an imaging or pharmacologic

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stress test, or to perform a retest on any of the non-invasive tests.

### II.4. Conclusion of Phase II.

Thus, Phase II of the invention provides a system which is able to recommend proposed diagnostic tests and treatments based on a set of test results, risk factors, and symptoms. This type of process is capable of being reproduced in other situations where a cause and effect is known between symptoms, risk factors, and test results.

Because the I/O is configured to require preceding fields of information to be entered before displaying later fields of information, the maximum amount of information is retained by the system, assuring the generation of complete records.

### III. Phase III - Report Generation and System Installation.

Phase III of the invention, shown in Figures 16, 17, 18, 19, 20, 21, 22A, 22B, 23, 24, 25A, 25B, 26 and 27, involves the generation of reports and statistical analyses by a system administrator. Preferably, the system administrator also installs the system and maintains the files, as shown in Figures 15 and 16.

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### III.1 The System Administrator

In the preferred embodiment, a system administrator has the relevant software files for Phases II and III installed, maintains the database 230, and generates reports/statistics. Normally, the present invention is

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provided with System Installation Software 245. This software, shown in the block diagram of Figure 15, is preset with a system administrator password.

A system administrator manual (not shown) will normally be provided with the System Installation Software 245 to assist the system administrator in configuring and maintaining the system. The system administrator manual will contain the preset password so that the system administrator may gain entry to the system. As shown in Figure 15, after startup 800, the system administrator enters the (preset) system administrator password 810. An exemplary screen display 815 for entering the system administrator password is shown in Figure 16.

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After entering the preset password, the system administrator will be presented with a number of options 812 for selection 814. The options, as shown in Figure 15, may be to install the system on a network 820 (network 210 and server 220 shown in Figure 2), install a workstation 830 (a computer 250, 280 shown in Figure 2), install a stand alone system 840 (not shown), or to install a software upgrade 850 (to either the network 210, server 220, or computers 250, 280 shown in Figure 2).

The network and workstation installations run together, on a network computer system, i.e. network 210 and computers 250 of Figure 2. In a networked system, the appropriate files are stored on the network server 220 and accessed by physicians at specified workstations, i.e. the computers 250, 280 shown in Figure 2.

The install network option 820 runs a routine which installs the

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relevant files on the network server 220 such as the database 230 (which is installed empty or with sample data) and installs the Administrative Software 240 on the Administration Computer 240. Next, the install workstation option 830 may be chosen, which runs a routine to install the Evaluation software 340 on the relevant computers 250, 280 Alternatively this option could be run at the computers 250, 280 to install the Evaluation Routine without using network communication.

The install stand alone option 840 runs a routine to install the database 230, the Administrative Software 330, and the Evaluation software 340 on a single computer.

The install upgrade option 850 runs a routine which adds new files or overwrites previously installed files with the latest version of the software. This enables additional features to be added yet maintains the integrity of the system.

After installation, the system administrator can run the Administrative Software 330. Figure 17 shows a block diagram of the Administrative Software.

First, the system administrator enters the system administrator password. The previously mentioned screen 815 of Figure 16, may be used to enter the password.

A number of options 875 are displayed 870 for selection by the administrator 880. The options, shown in Figure 18, are "system maintenance," "generate reports," or "statistics."

If "system maintenance" is selected, the System Maintenance Routine

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890 is executed. A sample screen display 895 for the System Maintenance Routine is shown in Figure 19. This routine allows standard system maintenance operations to be performed. For example the system administrator may perform the following operations: edit patients (to add, delete or edit patients), edit consulting physicians (to add, delete or edit consulting physicians), edit primary physicians (to add, edit or delete primary physicians), edit facilities (to add, edit or delete facilities), and set system password. Additionally, the System Maintenance Routine 890 allows workups to be deleted and data to be exported for use in other application programs.

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When the system administrator desires to edit or add facilities, "edit facilities" option is selected and the list of prior facilities is displayed. The system administrator may select a prior facility and delete it, or select an "add facility" option (not shown) and enter the name of new facilities. If a facility is to be deleted, the system prompts the administrator with a warning message. The system may be configured so that the deletion of facilities also deletes the associated workups, or the system may require the workups to be individually deleted.

Adding, deleting and editing consulting physicians, primary physicians and patients is done in the same manner.

The delete workups option may be selected to delete a prior workup.

This may be necessary, for example, if a patient is deleted. It therefore becomes unnecessary to maintain the patient's workup. This may also be necessary if a physician runs a workup on a patient who does not meet the

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inclusion criteria. In this case the workup may be deleted to prevent the skewing of results in the reports. When the "delete workups" option (not shown) is selected, the list of workups is displayed on the screen. A workup may be highlighted and then deleted by the delete workup option.

To set the system password, the system administrator types in the prior password and the new password. Preferably the new password is entered twice to ensure that the system administrator has not mistyped the password.

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Additionally the database may be repaired by selecting a "repair database" option. This option basically rearranges the data within the database 230 to be more efficiently retrieved. This should normally be selected every thirty days, depending upon the frequency with which data is entered into the database.

An "export data" selection is provided by the System Maintenance Routine 890, as shown in Figure 19. Figure 20 shows sample screen displays of the "export options" 897 and "export file name" screens 899 from the "export data" selection. The "export data" selection is used to output data to different types of application programs, such as spread sheets or word processors. In a preferred embodiment, shown in Figure 20, the type of information to export may be selected, i.e., pretest assessment, stress test, angiograms. The information for all of the physicians, or for specifically selected physicians, may be selected for export. Further, the information from a specific date range or all date may be selected. Additionally, a record header may be selected for inclusion with the field

names. The "export data" option is useful for exporting column headings to application programs. After selecting the data for export 897, the file type and file location 899 may be specified, as shown in Figure 20.

### III.2. Report Generation.

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A useful feature of the present invention is to generate reports of physician's activities or related to workups, facilities, or patients. As shown in Figure 17, a Report Routine 900 is provided. The Report Routine 900 generates different types of reports.

The system administrator may choose a type of report and then print or view the report. The types of reports are generally shown in Figure 21 (screen display 901) and include: workup table reports (workups, pretest assessments, stress tests, or angiograms) statistics (workups per physician, pretest assessments per physician, stress tests per physician, angiograms per physician) list table reports (tables of facilities, physicians, patients), and change table reports (tables of pretest assessment changes, stress test changes, angiogram changes).

A workup table report of stress tests 903 is shown in Figure 22A and Figure 22B. A statistics report of workups per physician 905 is shown in Figure 23. A list table report of physicians 907 is shown in Figure 24. A change table report of pretest assessment changes 909 is shown in Figure 25A and Figure 25B. The format and content of the reports is easily modified to include any data in the database.

As examples, the workup table reports may list tables of information related to evaluations. Specifically, the workups report may list workups by

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date, including patient name, physician name, facility and workup comments. The pretest assessment report may list the contents of the pretest risk screen for all workups, including symptoms and risk factors listed by workup date. The stress tests report 903 may list the results of all tests run on patients, by workup date (see Figure 22A and Figure 22B). The angiogram report may list the results of complete angiograms, by workup date.

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The statistical reports list statistics concerning the physicians. For example, the statistics could include the number of workups (Figure 23), pretest assessments, stress tests, or angiograms per physician. The workups per physician report 905 may list the number of completed and uncompleted workups performed by each physician. The pretest assessments per physician report may list the actions selected by physicians following the pretest risk assessment, including any guideline deviations. The stress tests per physician report may list the number of completed and uncompleted tests per physician. The angiograms per physician report may list a number of completed and uncompleted (pending or declined) angiograms performed per physician.

The list table reports generally list the facilities, physicians and/or patients. For example, the facilities report may list all the hospitals and clinics included in the database. The physicians report 907 may list all the physician information recorded in the database, including physician security numbers, as shown in Figure 24. The patients report may list the names and Social Security Numbers of the patients in the database.

The change table reports list changes made by the physician. For example, the pretest assessment changes report 909 may list all the changes made to previously recorded data on the pretest risk screen, as shown in Figure 25A and Figure 25B. The stress test changes report may list all changes made to previously recorded stress test results. The angiogram changes report may list all changes made to previously recorded angiogram results.

A report viewer is also included in the present system. The report viewer is shown in Figures 22A, 22B, 23, 24, 25A and 25B. Referring to Figure 22A, the report viewer 955 may list the number of database records queried 911 for the report, the number of database records that fit the query requirements 913, the number of records used for the report 915, and the percentage of queried records used for the report 917. The viewer also displays the contents of the report 919. Viewer commands include go to the first page of the report 921, go to the last page of the report 923, move ahead one page 925, move back one page 927, stop reading database 929 (if databases access is taking a long time), magnify 931, and print report 933, and may include other well known viewing commands.

The viewer enables the system administrator to quickly page through
the report for information needed by the health care provider's management
and to print the report.

### III.3. Statistical Graphs.

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Despite the statistics report, a separate Statistics Routine 910 (Figure

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17) is used to generate graphs of the data stored in the database. Figure 26 shows a screen display 941 for the Statistics Routine 910. As shown in Figure 19, the Statistics Routine generates statistics for the physicians, either separately or in a selected combination. The number of workups, pretest evaluations, stress tests, angiograms, pretest evaluation deviations, and stress test deviations per physician may be plotted. Additionally, the types of deviations (such as for deviations from pretest or stress test recommendations) may be plotted per physician. The graphs may be formatted for overall total numbers or broken down by physician (either by ID number or by name). Figure 27 shows a statistical graph 945 of workups per physician, by physician number.

The specific reports and statistical graphs listed herein are only for illustration only. It is to be understood that any information within the database may be included on a report or statistical graph.

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### IV. Phase IV- Updating the Phase II Embodiment.

In the fourth "phase" of the invention, the decision support recommendations of Phase II are periodically refined and updated after a review of the aggregate data and in view of the results of the latest research as determined by an expert review panel.

Phase IV involves the same basic steps shown in Figure 1, and is performed periodically to refine and update the phase II system. In Phase IV of the invention, advances in medicine occurring after the previous Phase I/II stages are considered, as relating to risk factors 70, presenting

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symptoms 50, diagnostic techniques 90, treatments 30 and other information (110), such as patient signs or the medical literature. Based on the prior knowledge base and the newly available information, the "best practice" knowledge base is updated.

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An important part of the Phase IV embodiment is an analysis, in the aggregate, of the stored evaluations/workups from the databases 230. This is shown at step 115 of Figure 1. Databases 230 contain actual data which was in many cases entered firsthand by physicians, often in the presence of their patients. Much can be learned from this data, including new risk factors, presenting symptoms, diagnostic techniques, treatments, or other information. The data is valuable because it is obtained firsthand from practicing physicians and relates to actual patients.

This phase makes use of all the prior workup data. Data entered by physicians when they do not select a recommended course of action, or select an option not provided for in the knowledge base (such as "other" as shown in the various screen displays) is especially helpful. This data provides new information which may be studied by experts in the field to improve the phase II "best practice" system.

The knowledge base is thus expanded using the experiences (evaluations) recorded in the database 230. New code is generated 130 and new I/O routines coded 140 to implement the new knowledge in the knowledge base. Coding the I/O routines preferably also involves generating "help" boxes to explain new options or input fields, or the latest advances incorporated into the system. Testing 180 is performed as before,

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and when complete an update or new program 190 is generated. The new program may be installed as shown and described with respect to Figures 15-16. A program update may be installed as shown at option 850 in Figure 15.

Thus, Phase IV updates the present invention to incorporate the latest knowledge in the medical field. Practicing physicians who use the present invention in Phase II may at once alter their practices without training to implement the newest advances in medicine, as they perform and store workups which will be used in the future to further advance the field.

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The foregoing description of the present invention has been presented for purposes of illustration and description. Furthermore, the description is not intended to limit the invention to the specific embodiments described. Consequently, variations and modifications commensurate with the above teachings, and within the skill and knowledge of the relevant art, are part of the scope of the present invention. The embodiments described hereinabove are further intended to explain best modes known of practicing the invention and to enable others skilled in the art to utilize the invention in such, or other embodiments and with various modifications required by the particular application or use. It is intended that the appended claims be construed to include alternative embodiments to the extent permitted by law.

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Appendix

**EXERCISE Stress Test Logic** 

Risk HIGH HIGH HIGH HIGH INDETERMINATE		INDETERMINATE INDETERMINATE INDETERMINATE INDETERMINATE	INDETERMINATE INDETERMINATE INDETERMINATE INDETERMINATE	INDETERMINATE INDETERMINATE INDETERMINATE INDETERMINATE	HIGH INTERMEDIATE INTERMEDIATE INTERMEDIATE	INDETERMINATE INDETERMINATE INDETERMINATE
Lesuil Objective Result POSITIVE POSITIVE POSITIVE POSITIVE POSITIVE POSITIVE NEGATIVE NEGATIVE	NEGATIVE NEGATIVE INDETERMINATE INDETERMINATE INDETERMINATE	POSITIVE POSITIVE POSITIVE	NEGATIVE NEGATIVE NEGATIVE	INDETERMINATE INDETERMINATE INDETERMINATE INDETERMINATE	POSITIVE POSITIVE POSITIVE POSITIVE	NEGATIVE NEGATIVE NEGATIVE
Double Product Exercise. Time Subjective Result           <=3.00	POSITIVE POSITIVE POSITIVE POSITIVE POSITIVE	NEGATIVE NEGATIVE NEGATIVE NEGATIVE	NEGATIVE NEGATIVE NEGATIVE NEGATIVE	NEGATIVE NEGATIVE NEGATIVE NEGATIVE	POSITIVE POSITIVE POSITIVE	POSITIVE POSITIVE POSITIVE
c=3:00 3:01-6:00 6:01-9:00 >9:00 <=3:00	6:01-9:00 >9:00 3:01-6:00 3:01-9:00 >9:00	<pre>&lt;=3:00 3:01-6:00 6:01-9:00 &gt;9:00</pre>	3:01-6:00 6:01-9:00 >9:00	<=3:00 3:01-6:00 6:01-9:00 >9:00	<=3:00 3:01-6:00 6:01-9:00 >9:00	<=3:00 3:01-6:00 6:01-9:00
Double Pi   C   C   C   C   C   C   C   C   C	00091> 00091> 00091> 00091>	00091> 00091>	00091> 00091>	00091> 00091>	16000-19999 16000-19999 16000-19999	16000-19999 16000-19999 16000-19999
Protogol Balke Balke Balke Balke	Balke Balke Balke Balke Balke	Balke Balke Balke Balke	Balke Balke Balke	Balke Balke Balke Balke	Balke Balke Balke Dalke	Baike Baike Baike
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Test Type Exercise Exercise Exercise Exercise Exercise Exercise Exercise Exercise	Exercise Exercise Exercise Exercise Exercise Exercise	Exercise Exercise Exercise Exercise	Exercise Exercise	Exercise Exercise Exercise Exercise	Exercise Exercise Exercise Exercise	Exercise Exercise Exercise

Appendix: p. 2

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Logic	Sult Objective Result NEGATIVE	INDETERMINATE INDETERMINATE INDETERMINATE INDETERMINATE	POSITIVE POSITIVE POSITIVE	NEGATIVE NEGATIVE NEGATIVE NEGATIVE	INDETERMINATE INDETERMINATE INDETERMINATE	POSITIVE POSITIVE POSITIVE POSITIVE	NEGATIVE NEGATIVE NEGATIVE NEGATIVE	INDETERMINATE INDETERMINATE INDETERMINATE INDETERMINATE
EXERCISE Stress Test Logic	Dauble Product Exercise Tims Subjective Result 16000-19999 >9:00 POSITIVE	POSITIVE POSITIVE POSITIVE	NEGATIVE NEGATIVE NEGATIVE	NEGATIVE NEGATIVE NEGATIVE	NEGATIVE NEGATIVE NEGATIVE NEGATIVE	POSITIVE POSITIVE POSITIVE	POSITIVE POSITIVE POSITIVE	POSITIVE POSITIVE POSITIVE
EXERC	duct Exercise	<ul><li>&lt;=3:00</li><li>3:01-6:00</li><li>6:01-9:00</li><li>&gt;9:00</li></ul>	<=3:00 3:01-6:00 6:01-9:00 >9:00	<=3:00 3:01-6:00 6:01-9:00 >9:00	<=3:00 3:01-6:00 6:01-9:00 >9:00	00:6-10:9 00:6-10:9 00:9-10:6:00 00:6=0	<=3.00 3.01-6.00 6.01-9.00 >9.00	<=3:00 3:01-6:00 6:01-9:00 >9:00
	Double_Prod 16000-19999	16000-19999 16000-19999 16000-19999	66661-00091 66661-00091 66661-00091	16000-19999 16000-19999 16000-19999 16000-19999	16000-19999 16000-19999 16000-19999 16000-19999	20000-29999 20000-29999 20000-29999 20000-29999	20000-29999 20000-29999 20000-29999 20000-29999	20000-29999 20000-29999 20000-29999 20000-29999
	Protocol Balke	Balke Balke Balke Balke	Balke Balke Balke Balke	Balke Balke Balke Balke	Balke Balke Balke Balke	Balke Balke Balke Balke	Balke Balke Balke Balke	Baike Baike Baike Baike
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EXERCISE Stress Test Logic

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	Protocol	Bruce Bruce Bruce	Bruce Bruce Bruce Bruce Bruce	Bruce Bruce Bruce Bruce Bruce	Bruce Bruce	Bruce Bruce Bruce	Bruce
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IMAGING Stress Test Logic

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Protocol Bruce Bruce	Bruce Bruce Bruce	Bruce Bruce Bruce	Bruce Bruce Bruce	Bruce Bruce Bruce Bruce	Bruce Bruce Bruce	Bruce Bruce Bruce	Bruce Bruce Bruce Bruce
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PHARMACOLOGIC Stress Test Logic

Test_Type Pharmacologi	Test Type Test SubType Pharmacologi Adenosine Cardiolite	Heart Rate Dose 0	Dose 0	Subjective Result	Objective Result POSITIVE	Objective Special Res POSITIVE	Risk INTERMEDIATE
Pharmacologi	Pharmacologi Adenosine Cardiolite	0	0	<none></none>	POSITIVE	NEGATIVE	MO7]
Pharmacologi	Phamacologi Adenosine Cardiolito	0	•	<none></none>	POSITIVE	INDETERMINATE	INDETERMINATE
Pharmacologi	Pharmacologi Adenosine Cardiolite	0	0	<none></none>	NEGATIVE	POSITIVE	INTERMEDIATE
Pharmacologi	Pharmacologi Adenosine Cardiolite	0	•	<nqne></nqne>	NEGATIVE	NEGATIVE	ТОМ
Pharmacologi	Pharmacologi Adenosine Cardiolite	•	•	<none></none>	NEGATIVE	INDETERMINATE	INDETERMINATE
Pharmacologi	Pharmacologi Adenosine Cardiolite	0	•	<none></none>	INDETERMINAT	POSITIVE	INTERMEDIATE
Pharmacologi	Pharmacologi Adenosine Cardiolite	•	•	<none></none>	INDETERMINAT	NEGATIVE	TOW
Pharmacologi	Pharmacologi Adenosine Cardiolite	0	•	<none></none>	INDETERMINAT	INDETERMINATE	INDETERMINATE

## PHARMACOLOGIC Stress Test Logic

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-	Pharmacologi Adenosine Thallium	0	0	. <ndne></ndne>	NEGATIVE	NEGATIVE	MOT
-	Pharmacologi Adenosine Thallium	•	0	<none></none>	NEGATIVE	INDETERMINATE	INDETERMINATE
-	Pharmacologi Adenosine Thallium	•	0	<none></none>	INDETERMINAT	POSITIVE	INTERMEDIATE
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PHARMACOLOGIC Stress Test Logic

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PHARMACOLOGIC Stress Test Logic

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Subjective Result	POSITIVE	POSITIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE
POSITIVE	POSITIVE	POSITIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	
Dose 30 +	<b>9</b>	\$\$ \$\$	<30 30+	30 ¢	8 <del>\$</del>	8 ¢	8 4 8 4	<b>9</b> ¢	₽₽	8 4	₽ \$.
Heart Rate 125+	125+ 125+	125+ 125+	1254	125+ 125+	125+	125+ 125+	125+ 125+	125+ 125+	125+ 125+	125+	125+ 125+
Test Type Test SubType	Pharmacologi Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo
Pharmacologi Dobutamine Echo	Pharmacologi Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo	Dobutamine Echo
Test Type	Pharmacologi	Pharmacologi	Pharmacologi	Pharmacologi I	Pharmacologi I	Pharmacologi L	Pharmacologi D	Pharmacologi D	Pharmacologi D	Pharmacologi Do	Pharmacologi Dobutamine
Pharmacologi	Pharmacologi	Pharmacologi	Pharmacologi	Pharmacologi I	Pharmacologi I	Pharmacologi L	Pharmacologi D	Pharmacologi D	Pharmacologi D	Pharmacologi Do	Pharmacologi Dobutamine

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Test Type Pharmacologi	Test Type Test SubType Pharmacologi Persantine Cardiolite	Heart Rate Dose 0 0	Dose	Subjective Result	Objective Result POSITIVE	Objective Special Res POSITIVE	Risk INTERMEDIATE
Pharmacologi	Pharmacologi Persantine Cardiolite	0	0	<none></none>	POSITIVE	NEGATIVE	ГОМ
Pharmacologi	Pharmacologi Persantine Cardiolite	0	0	<none></none>	POSITIVE	INDETERMINATE	INDETERMINATE
Pharmacologi	Pharmacologi Persantine.Cardiolite	0	•	<none></none>	NEGATIVE	POSITIVE	INTERMEDIATE
Pharmacologi	Pharmacologi Persantine Cardiolite	0		<none></none>	NEGATIVE	NEGATIVE	LOW
Pharmacologi	Pharmacologi Persantine Cardiolite	•		<none></none>	NEGATIVE	INDETERMINATE	INDETERMINATE
Pharmacologi	Pharmacologi Persantine Cardiolite	•	•	<none></none>	INDETERMINAT	POSITIVE	INTERMEDIATE
Pharmacologi	Pharmacologi Persantine Cardiolite	•	•	<none></none>	INDETERMINAT	NEGATIVE	TOW
Pharmacologi	Pharmacologi Persantine Cardiolite	0	•	<none></none>	INDETERMINAT INDETERMINATE	INDETERMINATE	INDETERMINATE

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Test_Type Pharmacologi	Lest Dyce Lest SubDyce Pharmacologi Persantine Thallium	Heart Rate Dose 0 0	Dose 0	Subjective Result	Objective Result POSITIVE	Objective Special Res POSITIVE	Risk INTERMEDIATE
Pharmacologi ,	Pharmacologi Persantine Thallium	•	0	<none></none>	POSITIVE	NEGATIVE	TOW
Pharmacologi Persa	Persantine Thallium	. 0	•	<none></none>	POSITIVE	INDETERMINATE	INDETERMINATE
Pharmacologi	Pharmacologi Persantine Thallium	0	0	<none></none>	NEGATIVE	POSITIVE	INTERMEDIATE
Pharmacologi	Pharmacologi Persantine Thallium	•	•	<none></none>	NEGATIVE	NEGATIVE	MO7
Pharmacologi	Pharmacologi Persantine Thallium	•	0	<none></none>	NEGATIVE	INDETERMINATE	INDETERMINATE
Pharmacologi	Pharmacologi Persantine Thallium	•	•	<none></none>	INDETERMINAT POSITIVE	POSITIVE	INTERMEDIATE
Pharmacologi	Pharmacologi Persantine Thallium	•	•	<none></none>	INDETERMINAT	NEGATIVE	MO7
Pharmacologi	Pharmacologi Persantine Thallium	•	•	<none></none>	INDETERMINAT	INDETERMINAT INDETERMINATE	INDETERMINATE

## We claim:

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1. A method for developing a knowledge base related to a medical condition and its causes, comprising the steps of:

identifying the medical condition;

identifying presenting symptoms which support or rebut the presence of the medical condition in a patient;

analyzing the identified information using a best practice approach in order to determine whether the patient has the medical condition based on the identified information, including the step of considering other information tending to support or rebut the presence of the medical condition;

building a knowledge base using the analyzed information.

- 2. The method of claim 1, further comprising the steps of:
- identifying risk factors for the medical condition which tend to increase the probability that the medical condition exists;

wherein the step of analyzing includes the step of processing the risk factors.

20 3. The method of claim 1, further comprising the steps of:

identifying diagnostic techniques for the medical condition which lead to results tending to support or reject the existence of the medical condition in a patient;

wherein the step of analyzing includes the step of processing the

results obtainable via the diagnostic techniques.

- 4. The method of claim 1, further comprising the steps of: identifying treatments for the medical condition:
- wherein the step of analyzing includes the step of processing the treatments.
  - 5. The method of claim 1, further comprising the steps of:

identifying risk factors for the medical condition which tend to

10 increase the probability that the medical condition exists;

identifying diagnostic techniques for the medical condition which lead to results tending to support or reject the existence of the medical condition in a patient;

identifying treatments for the medical condition;

- wherein the step of analyzing includes the step of processing the treatments, the risk factors, and the diagnostic techniques.
  - 6. The method of claim 5, wherein the knowledge base is used to recommend actions to a physician, further comprising the steps of:
- coding the knowledge base into executable routines which recommend courses of action to a physician based on the problem, presenting symptoms, risk factors, diagnostic techniques, or treatments;

developing input/output routines for obtaining information concerning the problem, presenting symptoms, risk factors, diagnostic

techniques, or treatments;

integrating the input/output routines with the coded knowledge base to form an integrated system for recommending actions to physicians.

- The method of claim 6, further comprising the steps of: testing the integrated system for recommending actions to physicians; analyzing the results of the testing;
  - recoding the knowledge base to incorporate the analysis of the results of the testing;
- reintegrating the recoded knowledge base with the I/O routines to form a tested system for recommending actions to physicians.
  - 8. The method of claim 6, wherein the developing step comprises the steps of:
- awaiting sufficient input information before allowing the system to continue, to ensure that a complete record of input information is provided prior to proceeding to the next input or output.
- 9. The method of claim 6, wherein the medical problem is cardiac ischemia,20 and wherein the step of coding comprises:
  - providing the recommended actions from the set of: noninvasive testing, angiography, medical treatment of ischemia, no further testing.

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10. The method of claim 9, wherein the risk factors are age, HTN, smoker, family Hx, obesity, diabetes, dyslipidemia and known CAD; wherein the other information is anginal type and Canadian Anginal Classification, and wherein the noninvasive testing includes imaging stress testing, exercise stress testing, and pharmacological stress testing.

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11. The method of claim 6, wherein the integrated system is used as a decision support tool for working up patients, and wherein the integrated system stores patient workup data in a one or more databases, and wherein the step of analyzing further comprises the step of:

analyzing the aggregate workup data from the one or more databases.

- 12. A system for recommending actions, based on an analysis of entered information and a knowledge base, comprising:
- an input device for inputting information concerning a patient and for inputting selections;
  - a database, which stores information concerning patients;
  - a computer, in operative communication with the input device and database, which processes the input information according to a best practice process, and recommends one or more actions;
  - a display, connected to the computer, for displaying the recommended actions and other actions so that the input device may be used to select a displayed action.

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- 13. The system of claim 12, wherein the computer generates reports concerning the data stored in the database.
- 14. The system of claim 12, wherein the database is stored on a file server,and further comprising:

a computer network, connected to the computer and file server, which establishes communication between the database and the computer.

- 15. The system of claim 14, further comprising:
- a plurality of computers in operative communication with the computer network, each computer connected to a local input device and a local display and in operative communication with the database, each computer processing the local input information according to the best practice process, and displaying recommended actions and other actions on the computer display.
  - 16. A method for recommending proposed actions to physicians, comprising the steps of:

determining that a patient fits an inclusion criteria, which sets forth

20 a medical problem and the capabilities of a processing program to address
the medical problem;

entering data concerning the patient;

processing the patient data in a processing program, the processing using a best practice database to generate one or more recommended

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actions;

displaying possible actions the physician may take, including the recommended actions:

selecting a displayed action.

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17. The method of claim 16, further comprising the steps of:

determining whether the selected action was a recommended action or a nonrecommended action:

if the selected action is a nonrecommended action, prompting the physician to enter reasons why the selected action was taken.

18. The method of claim 16, wherein the data concerning the patient includes presenting symptoms, the method further comprising:

assessing that the patient has presenting symptoms sufficient for a physician to formulate an initial clinical impression, based on the best practice database;

selecting an initial clinical impression.

19. The method of clam 18, wherein the data concerning the patient20 includes risk factors, the step of processing further comprising:

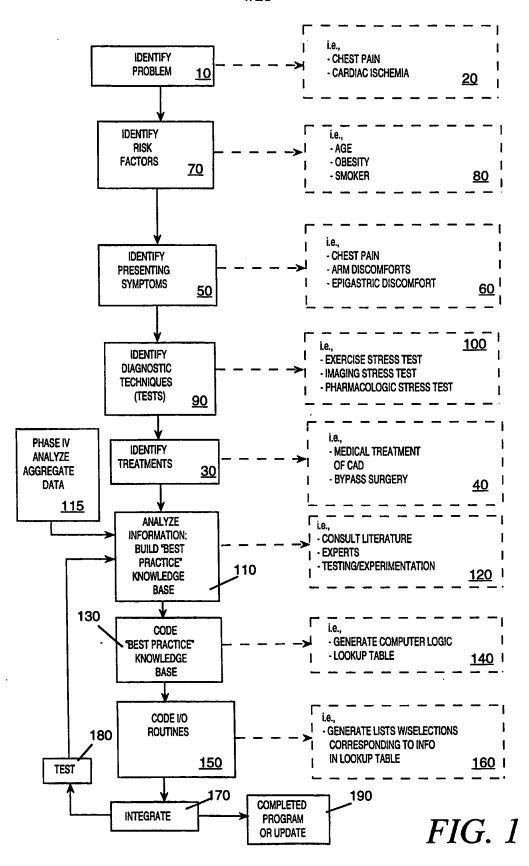
analyzing the risk factors to determine a pretest risk of the medical problem.

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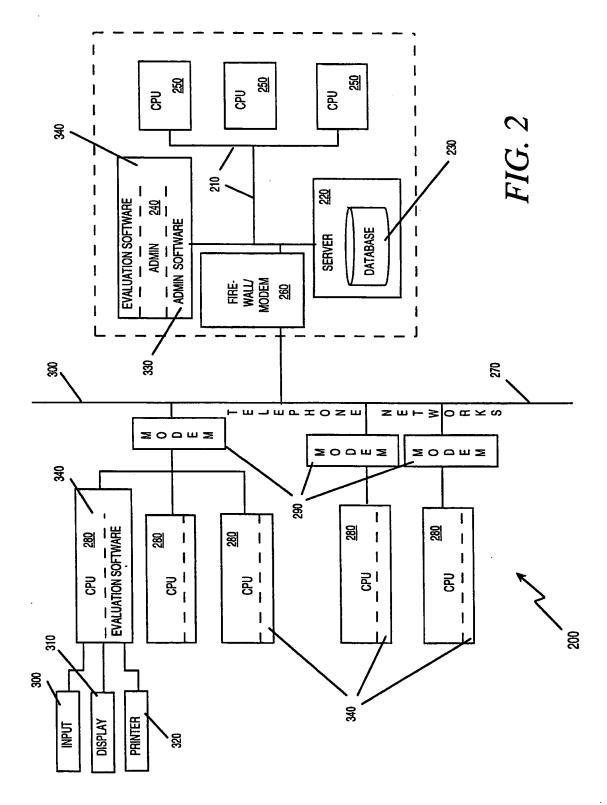
20. The method of claim 19, wherein the data concerning the patient includes test results, the step of processing further comprising:

analyzing the test results to determine a post test risk of the medical problem.

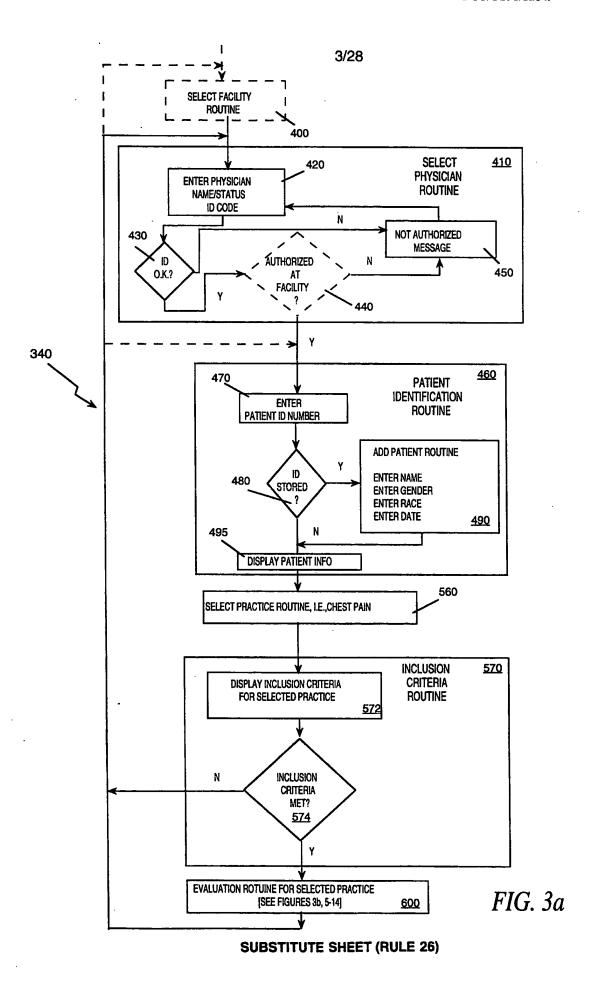




## **SUBSTITUTE SHEET (RULE 26)**



SUBSTITUTE SHEET (RULE 26)





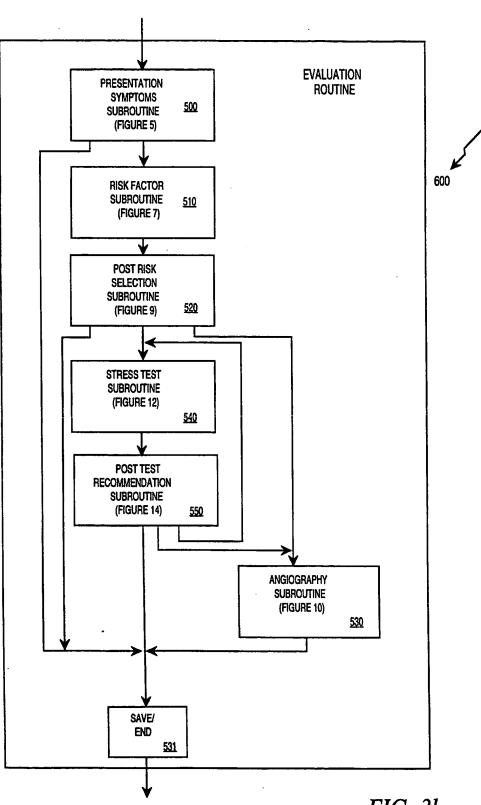
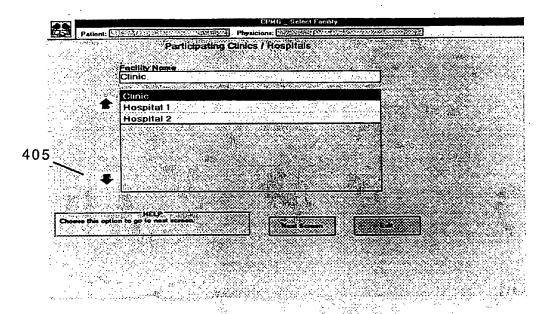
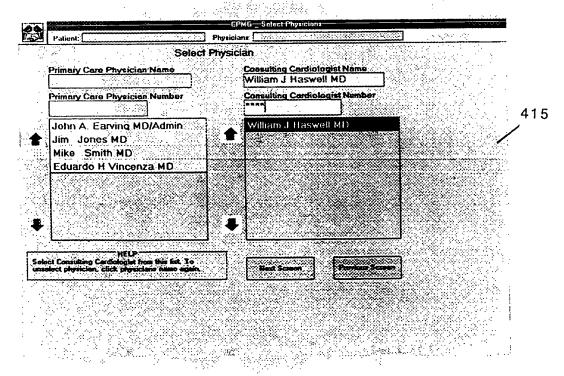


FIG. 3b

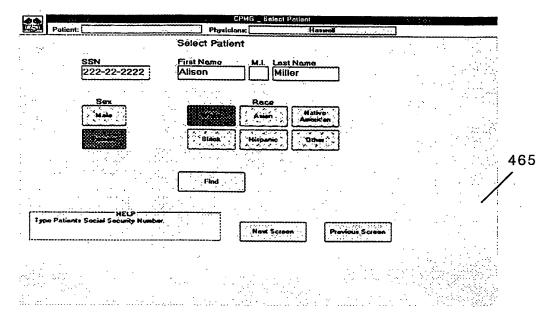
5/28 FIGURE 4A

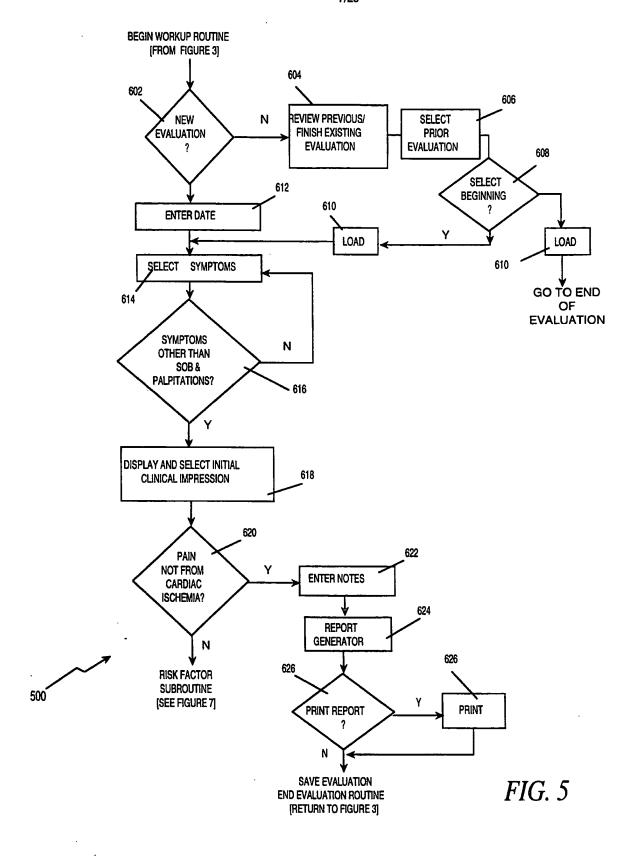


**FIGURE 4B** 



6/28 **FIGURE 4C** 





8/28 FIGURE 6A

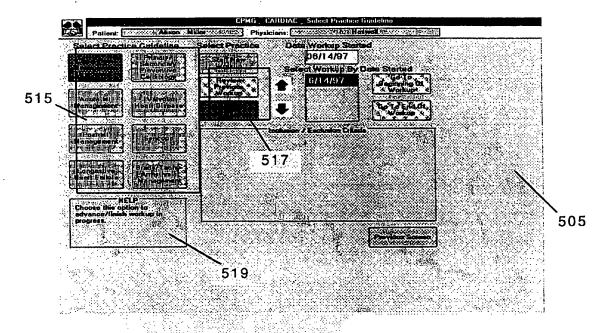
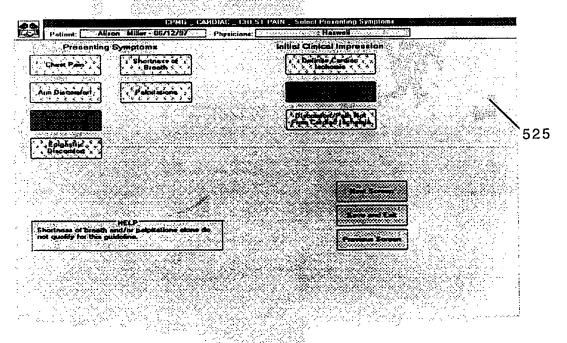
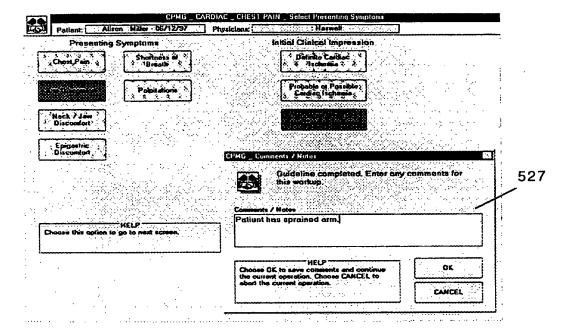
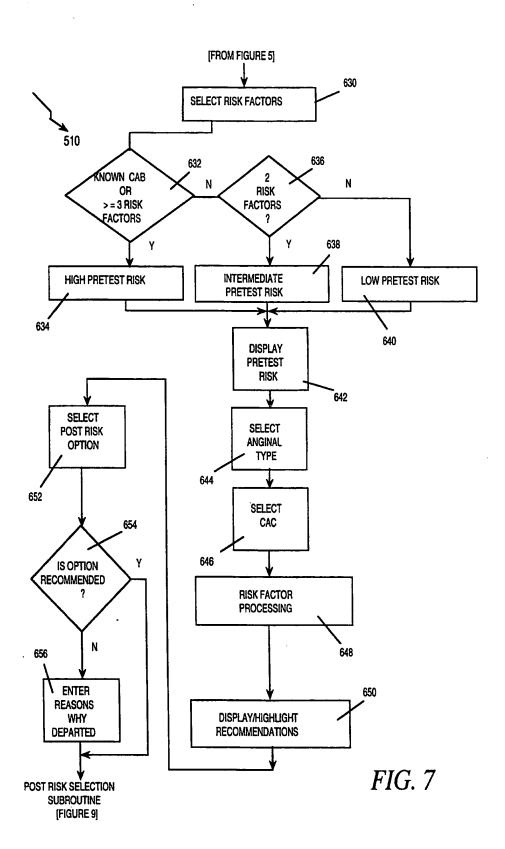


FIGURE 6B



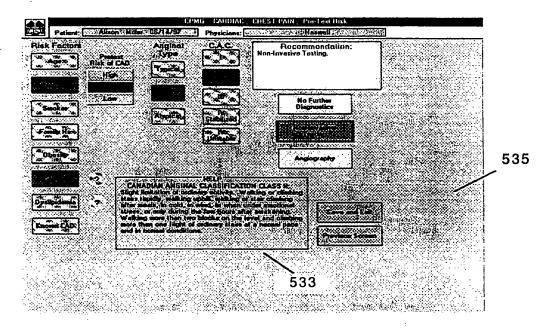
9/28 FIGURE 6C



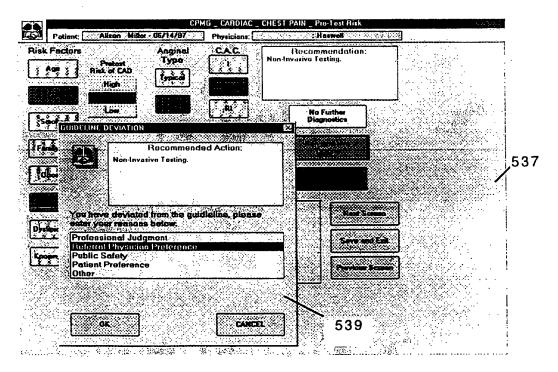


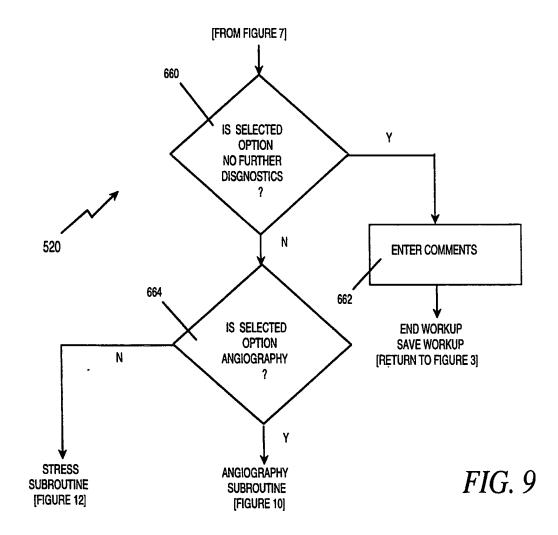
**SUBSTITUTE SHEET (RULE 26)** 

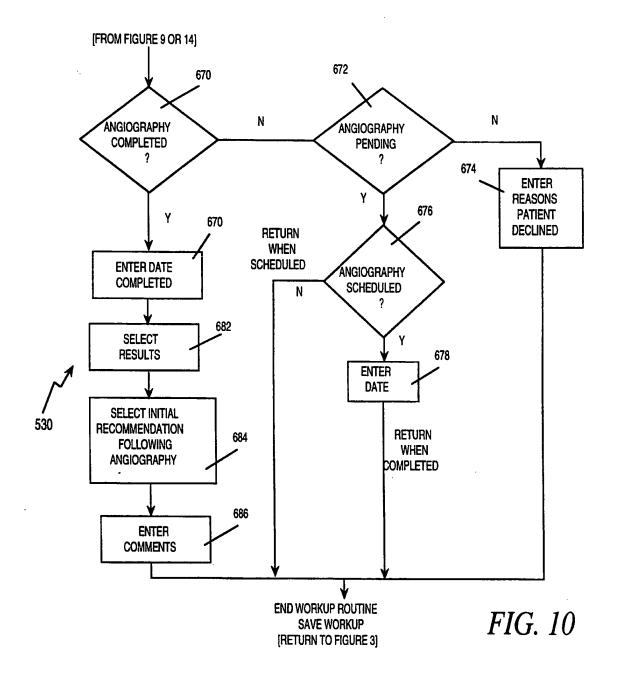
11/28 FIGURE 8A



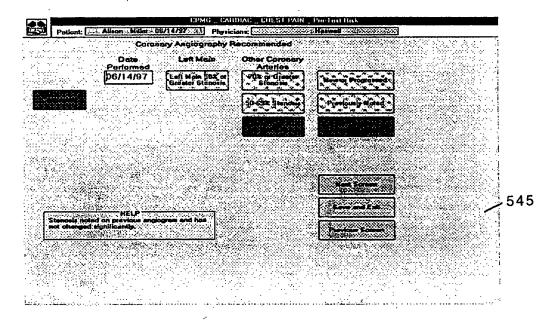
#### **FIGURE 8B**



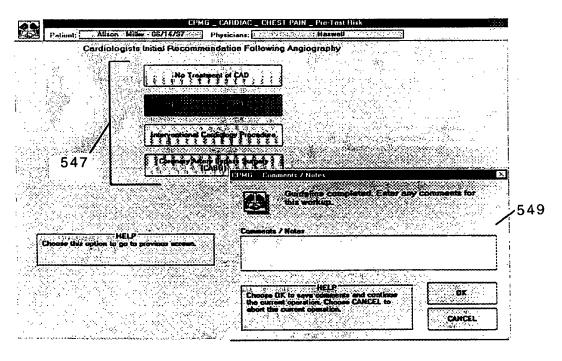


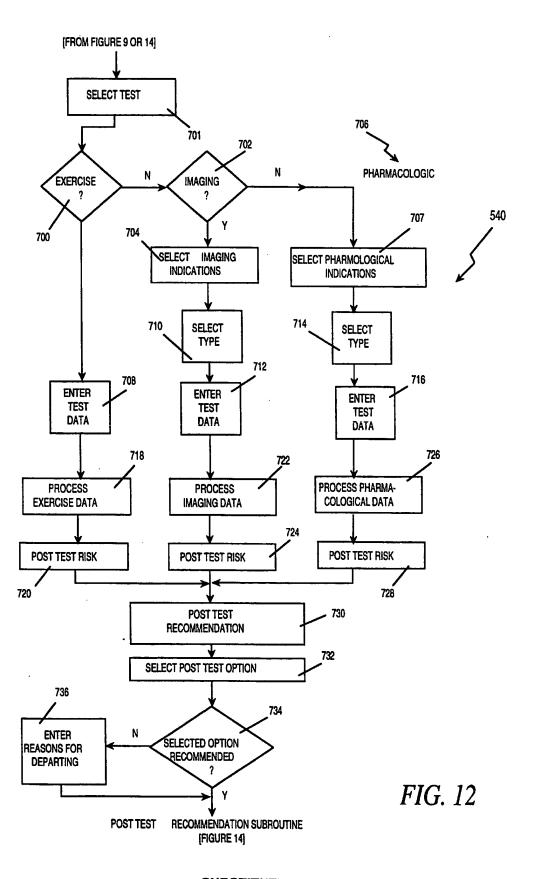


14/28 FIGURE 11A



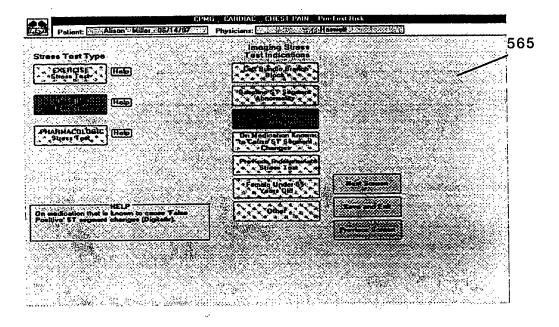
#### FIGURE 11B



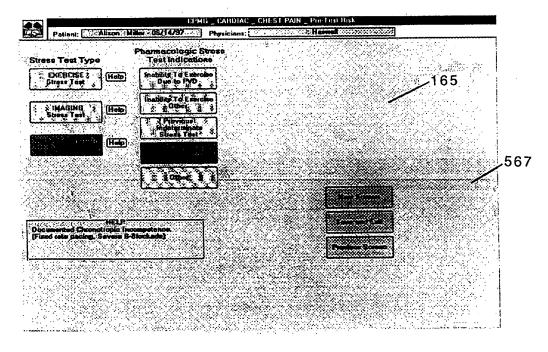


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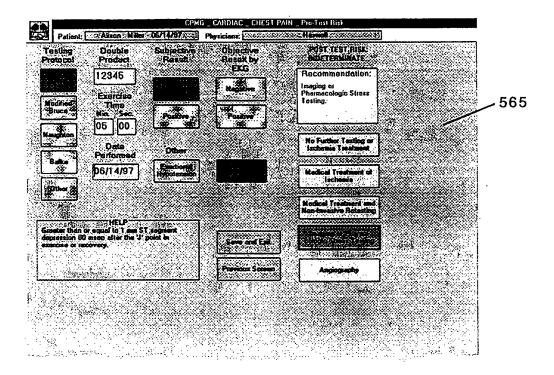
16/28 FIGURE 13A



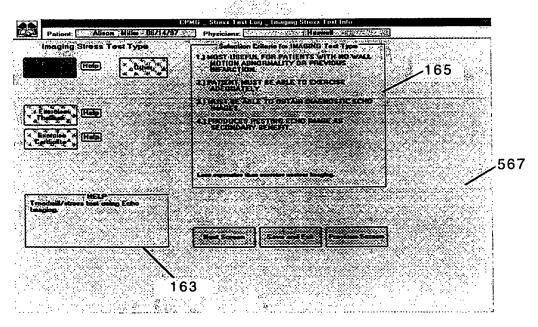
**FIGURE 13B** 



17/28 FIGURE 13C



#### FIGURE 13D



18/28 FIGURE 13E

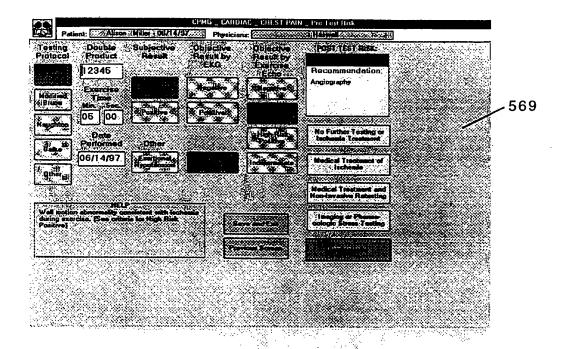
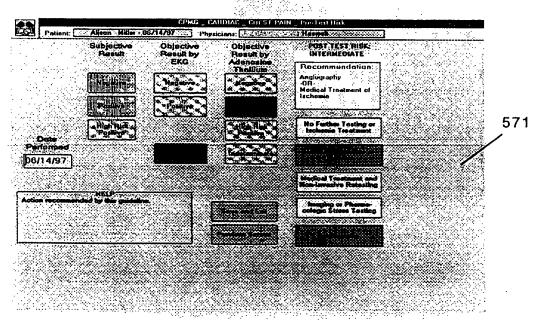


FIGURE 13 F



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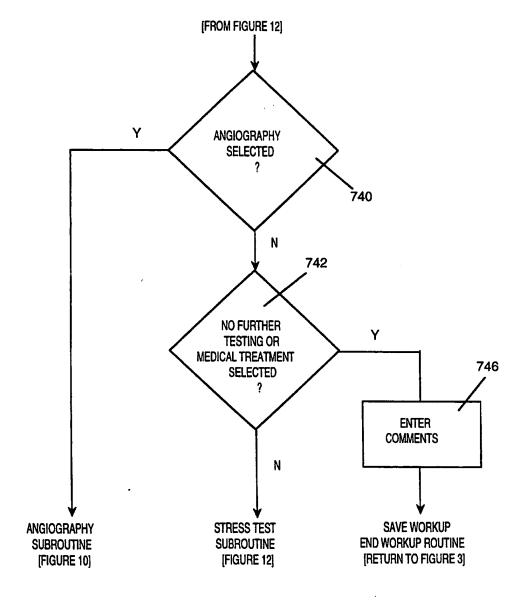


FIG. 14

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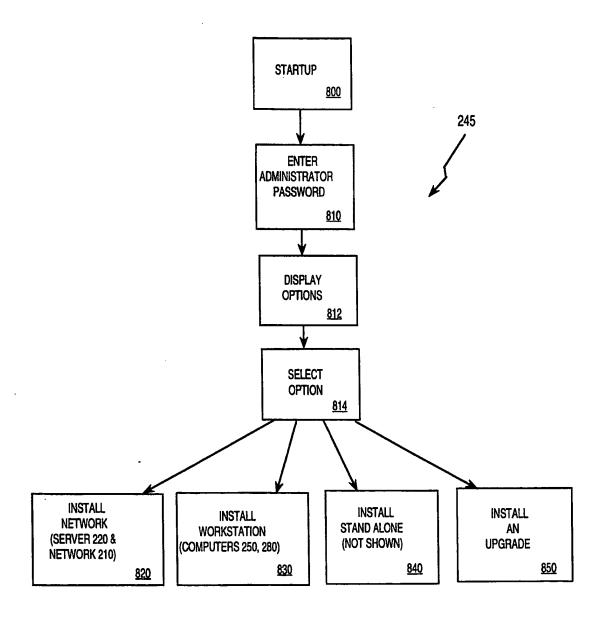
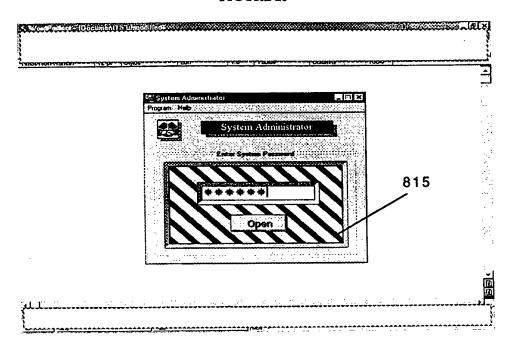


FIG. 15

21/28 FIGURE 16



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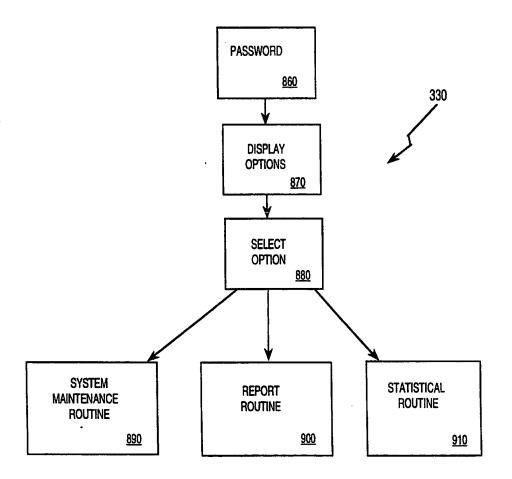
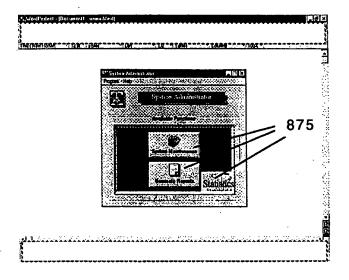
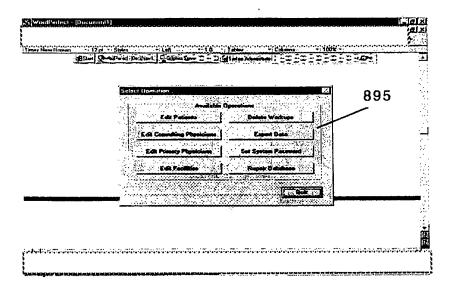


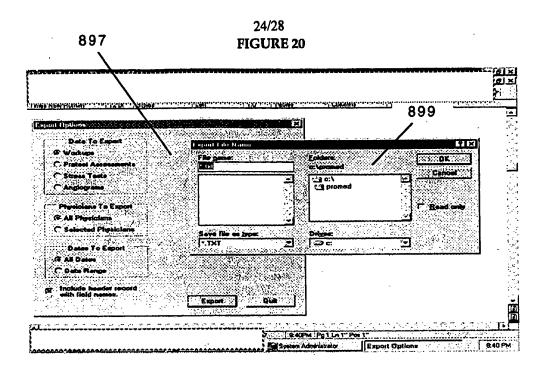
FIG. 17

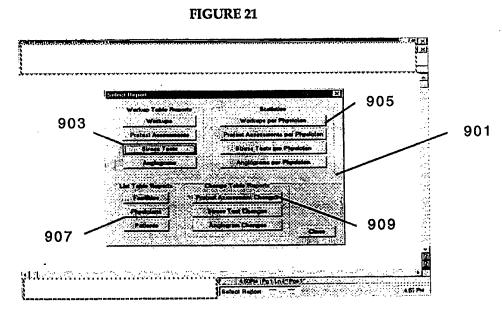
23/28 FIGURE 18



**FIGURE 19** 







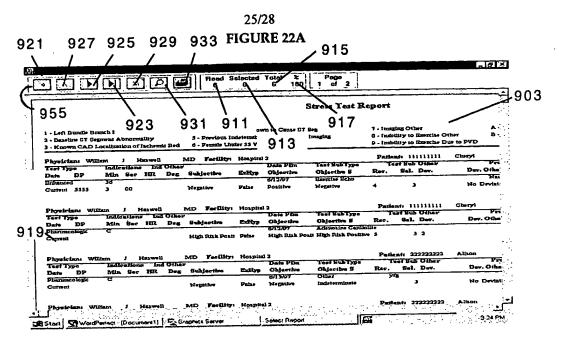
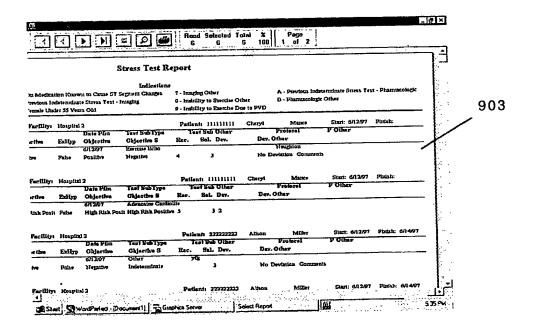


FIGURE 22B



26/28 FIGURE 23

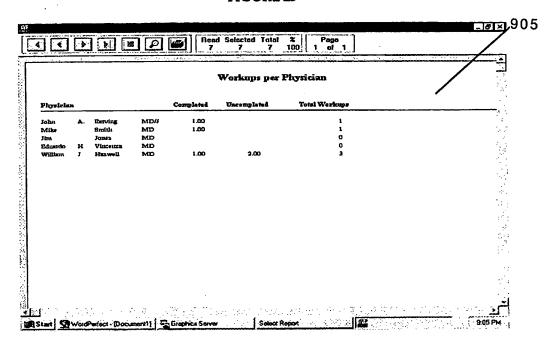
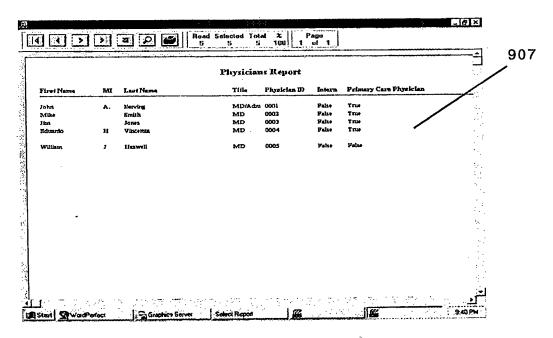
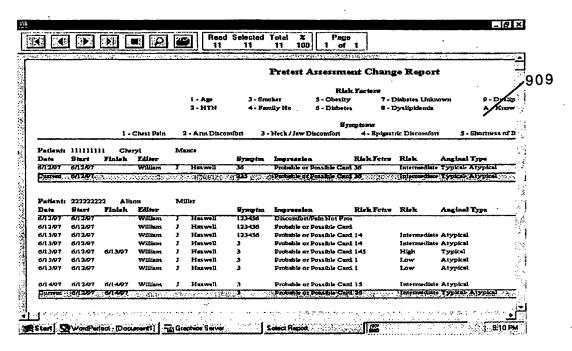


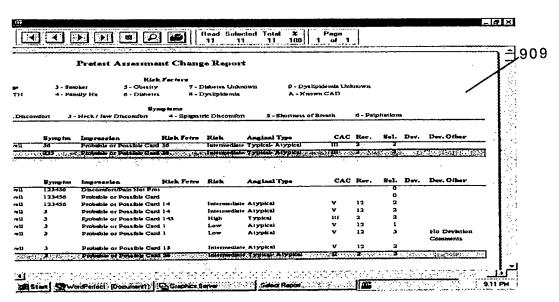
FIGURE 24

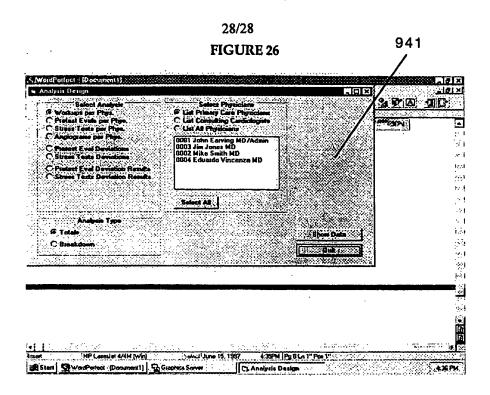


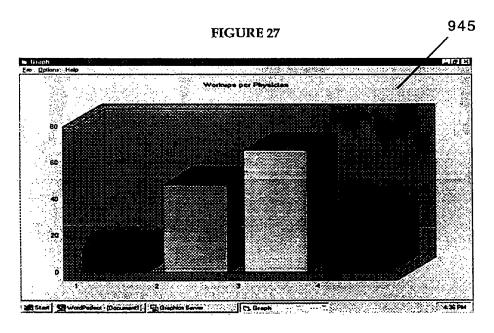
27/28 FIGURE 25A



**FIGURE 25B** 







### **PCT**

## WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



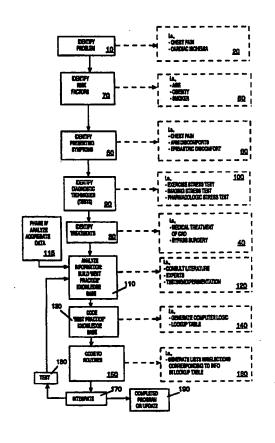
#### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> :  G06F 19/00, 9/44	A3	(11) International Publication Number: WO 98/58338  (43) International Publication Date: 23 December 1998 (23.12.98)
(21) International Application Number: PCT/US  (22) International Filing Date: 19 June 1998 (  (30) Priority Data: 60/050,978 19 June 1997 (19.06.97) 08/906,799 6 August 1997 (06.08.97)  (71) Applicant: PROMEDICUS SYSTEMS, INC. [US/US/Viking Drive, Eden Prairie, MN 55344 (US).	(19.06.9 (	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI,
<ul> <li>(72) Inventors: GRAHAM, Kevin, J.; 6512 Parkwood Roa MN 55436 (US). LESSER, John, R.; 165 Cristofo Orono, MN 55359 (US).</li> <li>(74) Agent: GLOVER, Gregory, J.; Dorsey &amp; Whitney L 200, 1330 Connecticut Avenue N.W., Washing 20036 (US).</li> </ul>	ori Circ LP, Su	le, With international search report.  (88) Date of publication of the international search report:  11 March 1999 (11.03.99

(54) Title: SYSTEM FOR PROVIDING RECOMMENDATIONS TO PHYSICIANS AND FOR MANAGING HEALTH CARE DATA

#### (57) Abstract

The present invention is directed to a system for supporting the decision making of a physician. Based on input data concerning a patient and a "best practice" knowledge base, the system provides recommendations to the physician, which the physician considers when deciding what action to take. The invention is also directed as helping to ensure that all the relevant data is input and stored in a relational database. The invention includes a method for setting up the "best practice" knowledge base, implementing the knowledge base, and improving the knowledge base using the data stored in the relational database. A specific embodiment directed to diagnosing and treating possible cardiac ischemia is disclosed.



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## INTERNATIONAL SEARCH REPORT

enational Application No PCT/US 98/12849

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CLASSIFIC	CATION OF SUBJECT MATTER G06F19/00 G06F9/44		
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	ENTS CONSIDERED TO BE RELEVANT		
ategory '	Citation of document, with indication, where appropriate, of the rel	evant passages	Relevant to claim No.
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